THE QUEEN'S AWARDS FOR ENTERPRISE 2001

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E.M.E. (Electro Medical Equipment) Ltd.

MK II Infant Flow™ Driver

Model M672B

Service Manual

Software Version 2.00

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Section 1

About this Manual

To assist the engineer and technician this manual contains full operating instructions for the Infant Flow™ System as well as detailed descriptions of all component parts of M672B, CE version MkII Infant Flow™ Driver from serial number 2000 up. For Drivers with serial numbers below 2000, refer to document M672SM. We suggest that all personnel involved in the service, repair or re-calibration of this product fully familiarise themselves with the clinical aspects and usage of the Infant Flow™ System as well as the mechanical and electronic intricacies as this will assist in front line service and troubleshooting.

The manual is split into several discreet sections which deal with the major sub-assemblies in order. This allows work to be undertaken in a logical and methodical manner on one section of the product without disturbing other parts. However, we recommend that the complete performance and verification procedure is carried out after any work has been carried out on any part of the Infant Flow™ Driver.

EME (Electro Medical Equipment) Ltd have a policy of continual improvement and update of all products. Technical bulletins are sent to all registered users of the company's products to keep them informed of any product changes. We welcome suggestions from users for product improvement and enhancement - please write to the either the Marketing or Research & Development departments with your comments.

Section 2

Product Description

The EME Mk II Infant Flow™ Driver is a combined Air/Oxygen Mixer, Oxygen Analyser, Flowmeter and Pressure Manometer with integral alarm systems designed specifically to be used in conjunction with the EME Infant Flow™ NCPAP Generator. Together these products make up the EME Infant Flow™ System.

The Infant Flow™ Driver is assembled in a sheet metal enclosure from standard and bespoke components. These are a Sechrist model 3500 Medical Air/Oxygen Mixer, a Dwyer Flowmeter calibrated for mixed gas between 0 and 15 lpm, a galvanic Oxygen Fuel Cell with associated electronics, a self activating electronic pressure measuring and limiting system and a mains power supply.

The Infant Flow™ Driver is supplied with a pole mount bracket to fit round or square section poles from 10 to 35 mm diameter or section. The gas inlet plate is pre-drilled with two pairs of M6 tapped holes to accommodate a variety of optional rail mount brackets.

The Medical Air and Oxygen gas inlets are either British Standard NIST or USA standard DISS fittings, other types can be supplied to special order. High pressure Medical Air and Oxygen hoses must be ordered separately specifying the length, colour and end fittings required.

The patient outlet is an ISO standard 15 mm female taper fitting and the pressure monitoring inlet is a standard Luer taper fitting. The Oxygen monitor is an integral part of the Infant Flow™ Driver and does not require any additional external fittings.

The Oxygen monitor uses a galvanic fuel cell sensor which is fitted in a pressure controlled path to avoid variations in delivered gas pressure altering the measured value. The gas which is used for the Oxygen analyser is subsequently vented from the rear of the Infant Flow™ Driver to avoid any risk of contamination to the patient.

Product Specification

Gas supply - Nominal 4 Bar (60 PSI) Clean, dry Medical Air and Oxygen.

Range - Minimum 2 Bar, maximum 6 Bar. Maximum differential pressure 2 Bar.

Power Supply - 200 to 265 VAC 0.10 A 50 to 60 Hz or 95 to 135 VAC 0.20 A 50 to 60 Hz.

Air/Oxygen Mixer - Range 21 to 100% Oxygen, accuracy + - 3% of selected output.

Flowmeter - Range 0 to 15 lpm, accuracy + - 5% of selected output.

Pressure relief valve - 2 systems fitted.

1 Patient safety - automatic electronic valve system pre-set to vent to ambient at 11 cms H_2O.

2 System & delivery circuit safety - mechanical internal relief valve pre-set at 150 cms H_2O.

Manometer - Range, 0 to + 12 cms H_2O, accuracy ± 1 cms H_2O.

Oxygen Monitor - Range 0 to 100% Oxygen, accuracy ± 2% of span.

Alarm System - Four separate alarm systems are provided all of which are automatic, the electronic alarms are set after 2 minutes operation without operator intervention although the operator can manually set or reset them if required.

1 Supply gases failure, if the differential pressure between the two inlet gases falls outside of the limit of 2 bar (30 PSI) or one gas fails completely an alarm will sound and the gas at the higher pressure only will be delivered to the patient.

2 High patient pressure, an audible and visual high pressure alarm is pre-set at 11 cms H_2O. This alarm automatically activates a pressure relieving solenoid which instantly reduces the pressure in the patient circuit to zero. A second high pressure alarm with audible and visual indication is set 3 cms H_2O above the measured CPAP pressure.

3 Low patient pressure, an audible and visual low pressure alarm is set at 2 cms H_2O below the measured CPAP pressure or at 0 cms H_2O if this would otherwise be negative.

4 Failure to deliver correct Oxygen concentration. Audible and visual alarms are provided at ± 5% of the set FIO_2 with an upper maximum limit of 101% and a lower minimum limit of 20%. There is a low hazard warning at 18% Oxygen or below.

Section 4

Summary of Warnings and Cautions

The EME Infant Flow™ Driver is a medical device intended for use only by qualified personnel under the direction of a qualified physician.

Personnel operating this equipment are responsible for reading and thoroughly understanding all product documentation provided. Statements throughout the product documentation have special significance as follows:

Key to Warnings, Cautions and Notes:

WARNING - Means there is a possibility of personal injury to the operator or patient.

CAUTION - Indicates there is a possibility of damage to the product or other equipment attached to it.

NOTE - Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment.

SUMMARY OF ALL WARNINGS, CAUTIONS AND NOTES CONTAINED IN THIS DOCUMENT:

WARNINGS

WARNING

Whenever a patient is attached to respiratory care equipment constant attendance is required by qualified personnel. The use of an alarm or monitoring system does not give absolute assurance of warning for every form of malfunction that may occur with the system. In addition, some problems may require immediate attention.

WARNING

Mixer must be corrected swiftly as the Oxygen concentration which was selected for the patient will not be delivered during an alarm/bypass situation.

WARNING

The gas mixer incorporated in this product is designed to mix Air and Oxygen only - do not modify the inlets to accommodate other source gases such as anaesthesia gases.

WARNING

Liquid water or other contaminants in either gas supply, particularly the air supply, will cause malfunction of this equipment and equipment connected to it.

WARNING

Oxygen vigorously accelerates combustion. To avoid explosion hazard do not use any instrument or other equipment that may have been exposed to oil or grease contamination.

WARNING

The gas failure alarm will not function if both supply gases are below 2 Bar.

WARNING

Ensure that the voltage set on the Infant Flow™ driver mains power input module is suitable for the local mains voltage. Equipment malfunction and overheating will result if incorrectly set.

WARNING

Nasal CPAP can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to usage guidelines will ensure that any incidence of these complications is kept to a minimum.

CAUTIONS

CAUTION

The precision gas mixing device incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.

CAUTION

Verify that this device has been authorised for use by qualified personnel.

CAUTION

Do not immerse any part of this device or gas or steam sterilise it. Damage will result.

NOTES

NOTE: EME recommend the use of a heated respiratory humidifier which utilises a heater wire in the inspiratory limb for enhanced patient safety.

NOTE: The gas failure alarm/bypass will activate when the first gas is connected and will reset upon connection of the second supply gas.

NOTE: We recommend between 36° and 37°C but never higher than 37°C.

NOTE: This figure is a general indication of how the devices are interconnected. The actual configuration may vary dependent on the ancillary equipment used.

NOTE: It is important that the tie straps are not over-tightened.

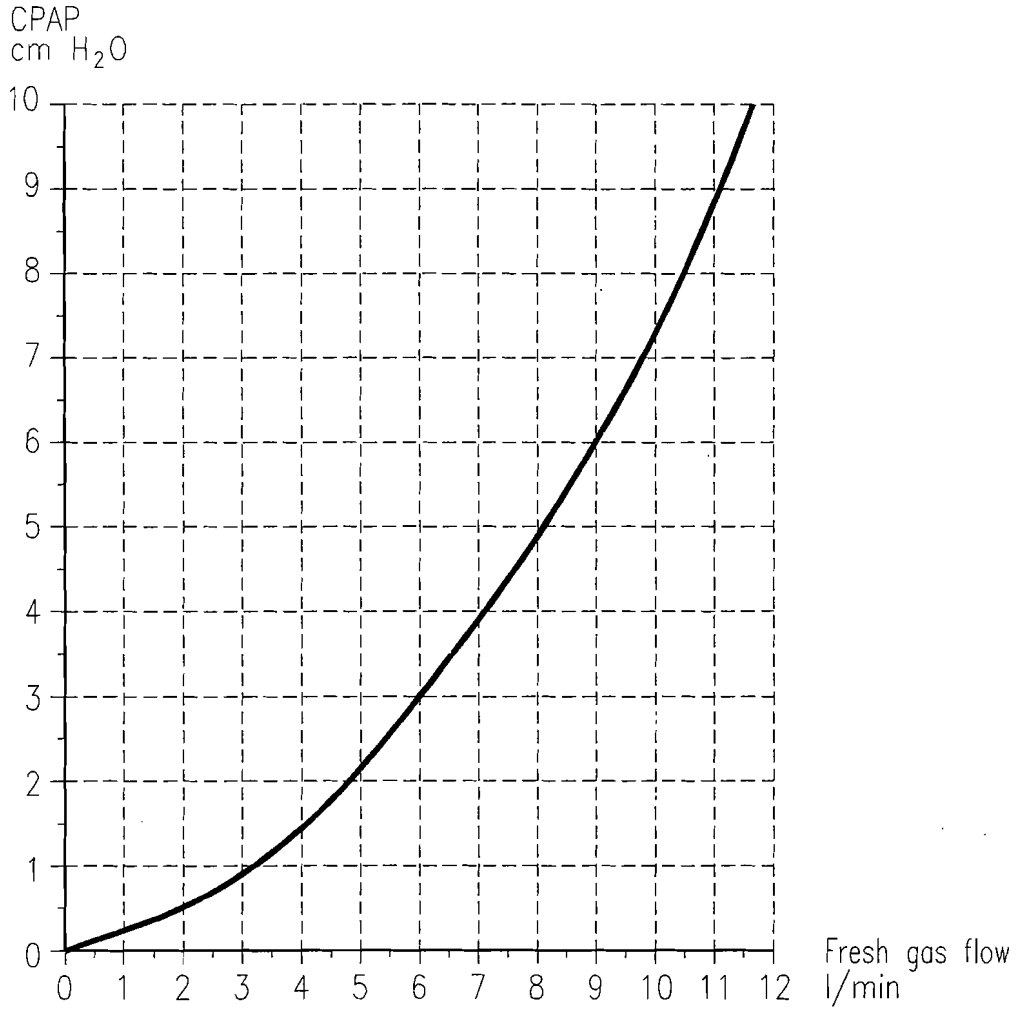
NOTE: It is recommended that hospital personnel responsible for the Performance Verification Test maintain records of their activities and identify equipment authorised for use.

Section 5

Operating Instruction

The Infant Flow™ system provides a virtually constant airway pressure irrespective of patient demand or expiratory flows via the specially designed generator nasal prongs. This is the reason for the Infant Flow's ability to provide superior CPAP. The Infant Flow™ generator is subject to a direct relationship between controlled enriched gas flow and CPAP pressure.

A nomogram illustrating the general relationship between constant airway pressure and flow settings is shown below. Example:- 8 lpm will provide in the order of 5 cms H_2O Nasal CPAP. Please note that actual devices may demonstrate tolerances of more than 10% from that illustrated in the nomogram and, in particular, at pressures below 2 cms.



Flow Pressure Nomogram for the EME Infant Flow System

CAUTION

Verify that this device has been authorised for use by qualified personnel.

1 Firmly mount the Infant Flow™ driver on either the pole and stand or the rail system with all of the ancillary equipment such as the Heated Respiratory Humidifier.

NOTE: EME recommend the use of a heated respiratory humidifier which utilises a heater wire in the inspiratory limb for enhanced patient safety.

2 Connect the Medical Air and Oxygen hoses to the Infant Flow™ Driver and then to the high pressure source.

NOTE: The gas failure alarm/bypass will activate when the first gas is connected and will reset upon connection of the second supply gas.

WARNING

Liquid water or other contaminants in either gas supply, particularly the air supply, will cause malfunction of this equipment and equipment connected to it.

3 Connect the power cord for the Infant Flow™ Driver to a suitable outlet, do not switch on the driver at this point.

4 Connect the patient circuit and Infant Flow™ generator as shown in figure 2.

NOTE: This figure is a general indication of how the various devices may be interconnected in a typical setup. The actual configuration will vary dependent on the type of ancillary equipment used.

5 Set the required FIO_2 using the calibrated knob on the Air/Oxygen mixer section of the Infant Flow™ driver.

6 Set the flowrate to give the prescribed NCPAP pressure using the Nomogram on page 9 as a reference.

7 Set the desired delivery temperature on the heated respiratory humidifier and switch it on.

NOTE: We recommend between 36° and 37°C but never higher than 37°C.

8 Select the appropriate size bonnet for the patient and fit it on the head of the patient as shown on the patient connection guide attached to the Infant Flow™ Driver.

9 Select the correct size nasal prongs and connect the Infant Flow™ Generator to the patient as shown in the patient connection guide and attach to the bonnet with the tie straps.

NOTE: It is important that the tie straps are not over-tightened.

10 Switch on the power to the Infant Flow™ Driver and ensure that the NCPAP pressure is that which is prescribed. Minor variations between devices occur but the pressure delivered should always be within ± 10% of those shown on the Nomogram. If they are out of specification perform the following checks. The pressure bar graph has been colour coded for ease of use. The "Normal Range" section of the bar graph indicates the most commonly used pressures with the Infant Flow™ generator. However, the actual

pressures used for the treatment of individual patients must be prescribed by the clinician.

a) Ensure that there are no leaks in the patient circuit.

b) Ensure that the Infant Flow™ generator has the correct size nasal prongs and that they are properly fitted in the patients nostrils.

11 The electronic alarms will automatically set after a 2 minute stabilisation period. Should you wish to set them earlier simply hold the Arm/Mute button in for three seconds. The alarm will bleep to indicate that your command has been accepted and the Alarms Armed indicator will illuminate.

12 Should you change the NCPAP treatment pressure or the Oxygen concentration it is necessary to reset the alarm levels by holding the Arm/Mute button in for three seconds.

13 What to do if an alarm occurs - Always attend alarm conditions immediately as the patient may not be receiving the prescribed FIO_2 or NCPAP.

There are two distinct types of alarm fitted in the Infant Flow™ Driver. The Air/Oxygen Mixer has a mechanical bypass and alarm system fitted which will sound if one of the supply gases is below or above the range of pressure which can be handled satisfactorily.

The second alarm system consists of an electronic system built into the pressure and Oxygen monitoring module. This has several functions as shown in the table overleaf. All electronic alarms with the exception of the overpressure alarm are self re-setting. In the event of an overpressure being detected the Driver activates a vent to ambient solenoid valve which removes gas flow from the patient circuit.

WARNING

Nasal CPAP can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to usage guidelines will ensure that any incidence of these complications is kept to a minimum.

14 NCPAP is not a benign procedure, all operators must be aware of the possible hazards and complications associated with this treatment. Operators must apply all necessary precautions to ensure safe and effective application and treatment.

- Do not over-tighten the prong fixation
- Always choose the correct size of prong

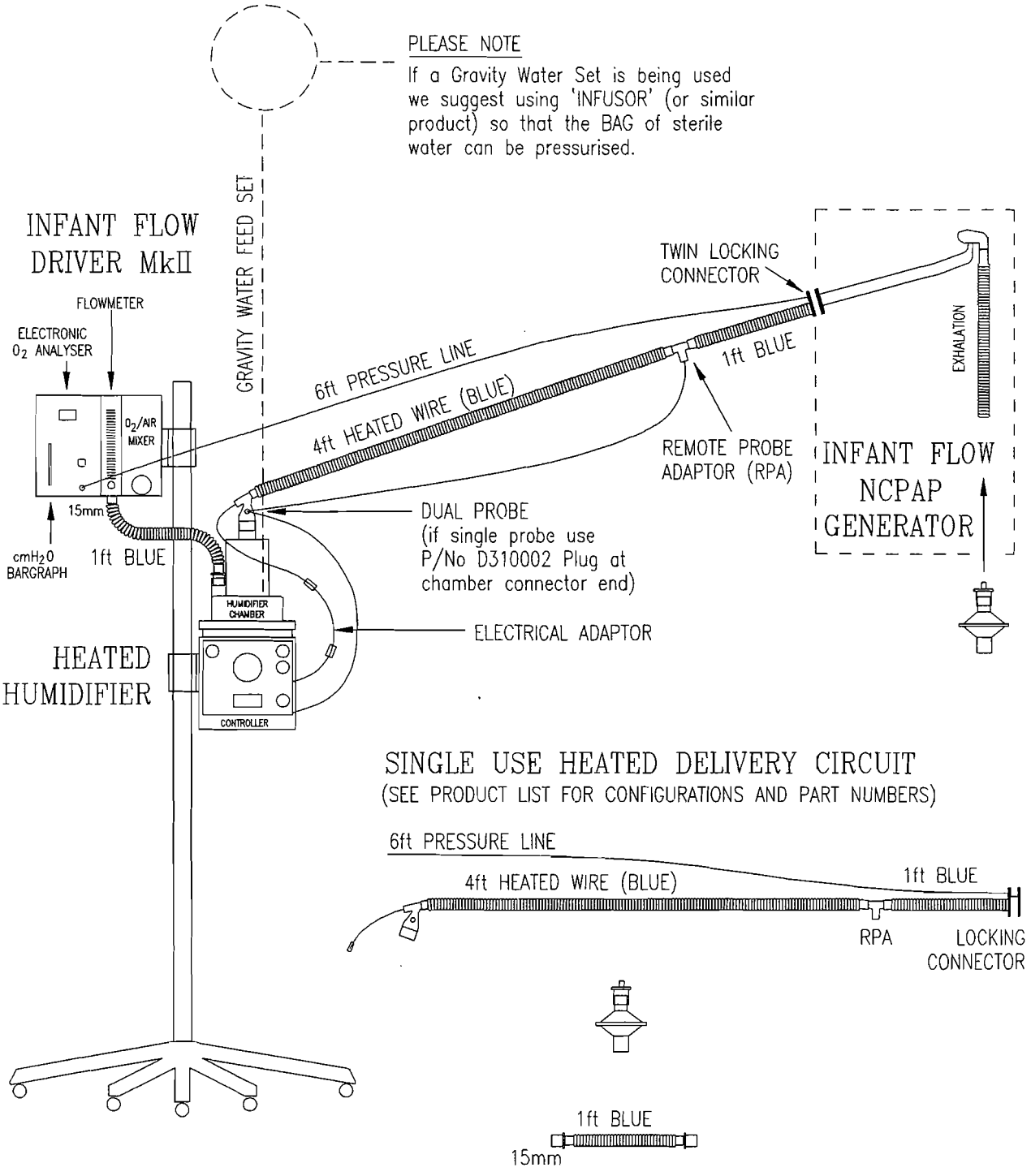
Check the nares every four hours for the following:

- Nasal irritation and septal distortion
- Skin irritation and pressure necrosis
- Nasal mucosal damage due to lack of humidification
- Gastric insufflation and abdominal distension

Model M672B Infant Flow™ Driver Alarm Systems		
Alarm function	Indication	Operator Action
Oxygen supply failure	Loud whistle	Check and restore Oxygen supply
Air supply failure	Loud whistle	Check and restore Air supply
High Oxygen Concentration	Audible alarm & High O_2 indicator illuminated	Check supply gases and galvanic fuel cell. Press the Arm/Mute button to silence the audible alarm
Low Oxygen Concentration	Audible alarm & Low O_2 indicator illuminated	Check supply gases and/or the galvanic fuel cell. Press the Arm/Mute button to silence the audible alarm
High Pressure	Audible alarm & High pressure indicator illuminated	Check the flowrate and check for occluded tubes. Press the Arm/Mute button to cancel the alarm or restore pressure in the circuit
Low Pressure	Audible alarm & low pressure indicator illuminated	Check the flowrate and check for occluded or disconnected tubes or nasal prongs. Press the Arm/Mute button to silence the audible alarm

EME Infant Flow™ NASAL CPAP SYSTEM

HEATED HUMIDIFIER AND HEATED WIRE DELIVERY CIRCUIT



NB It is a Dept of Health recommendation that an Oxygen Analyser be used at ALL TIMES when Oxygen Enriched Gases are being administered.

311-012

Section 6

Performance Verification Procedure

This performance verification procedure provides a means of determining whether the EME Infant Flow™ Driver meets its design specifications. These tests are intended to be performed in the Hospital by qualified personnel. The procedure should be performed at least every four months or more frequently if desired or if the device is suspect.

The check list must be followed exactly and if the Infant Flow™ Driver fails to meet any specifications it should be removed from service until calibration and/or service is accomplished.

Service of the EME Mk II Infant Flow™ Driver should only be undertaken by qualified technicians trained in the calibration, service and repair of devices of this nature and who have access to the special tools and equipment that are required. If this is not feasible contact EME or an authorised distributor to insure full reliability and safety of the product.

NOTE: It is recommended that hospital personnel responsible for the Performance Verification Test maintain records of their activities and identify equipment authorised for use.

WARNING

Oxygen vigorously accelerates combustion. To avoid explosion hazard do not use any instrument or other equipment that may have been exposed to oil or grease contamination.

The tests are divided into three parts, the first for the Air/Oxygen mixer, the second for the pressure manometer and the third for the Oxygen Analyser.

Some special equipment is necessary to perform the tests fully, this includes an accurate water manometer, adjustable regulators and an accurate Oxygen analyser. Do not attempt to perform the tests without suitable equipment.

First Test - Air/Oxygen Mixer

Connect the Infant Flow™ Driver to supply gases which are adjustable from 0 to 4 Bar or more. This can be achieved using adjustable regulator sets, EME Part No SG100.

Overall Accuracy - Set both supply gas pressures to 4 Bar. Select a flow of 15 lpm on the Flowmeter. Compare the Oxygen analyser readings to mixer % settings of 21, 40, 60, 80 and 100%. The mixer has a specified accuracy of ± 3%. If the Oxygen analyser is accurate to within ± 1% the setting and the analyser should agree within ± 4% at the various settings.

Accuracy with varying inlet pressures - Select an FIO_2 of 60% and observe the reference Oxygen analyser reading obtained with equal inlet pressures (4 Bar each). Vary the inlet pressures to the mixer to 3 Bar Oxygen and 4 Bar Air and then 4 Bar Oxygen and 3 Bar Air. Note the Oxygen analyser reading at each extreme and verify that the Oxygen reading does not vary by more than 1% at each extreme.

Alarm module test - Starting with the Oxygen and Air supplies at 4 Bar and an FIO_2 of 60% (the alarm should be silent) reduce the air inlet supply to 2 Bar or just under. The alarm should sound and the Oxygen analyser should read 100%. Increase the air supply pressure slowly, the alarm should cut out at around the 3 Bar level. Repeat the procedure varying the Oxygen pressure. When the alarm sounds the Oxygen analyser reading should drop to 21%.

Observe the Air inlet filter. If this is dirty or wet it should be replaced.

Second Test - Pressure Manometer

Tee an accurate water column with the hand pump bulb in line into the pressure input port on the front panel of the electronic module. Check that the manometer is at Zero then inflate the system to 10 cms H_2O and observe that the bar graph display illuminates and indicates 10 cms H_2O. If it doesn't, refer the device for full calibration.

Press the Arm/Mute button for 3 seconds to set the alarms and then increase the pressure to 11 cms H_2O, at this point the pressure vent valve should operate and the alarm sound. Increase the pressure to over-range the bar graph and ensure that all of the LEDs light up. Release the pressure in the system.

Press the Arm/Mute button again to reset the system and inflate to 5 cms H_2O. Reset the alarms and allow the pressure to drop to Zero. Observe that the low pressure alarm activates immediately. Press the Arm/Mute button, this should silence the alarm. Restore the pressure to 5 cms H_2O and observe that the visual alarm cancels.

Set the pressure to 8 cms H_2O and observe that the high alarm activates after 15 seconds. Drop the pressure to 3 cms H_2O and observe that the high alarm cancels and that the low alarm activates after 15 seconds.

Third test - Oxygen Analyser

Set the FIO_2 to 21% and the flowrate to 8 lpm, observe that the Oxygen reading is 21%. If it is not adjust the lower potentiometer accessible from the left hand side of the driver to read 21%.

Set the FIO_2 to 100% and observe that the Oxygen analyser reads 100% after 1 minute. If it is not adjust the upper potentiometer accessible from the left hand side of the driver to read 100%. If adjustments are found to be necessary repeat this procedure two or three times as there may be some small interaction between the controls.

Additional Information on Oxygen Fuel Cells

Material Safety Data: Product Name - Class R-22TED Oxygen Sensor

Physical & Chemical Data: Potassium Hydroxide (KOH) 15% Granular
Lead (Pb) Pure

Health Hazard Data: Primary routes of entry: Ingestion, Eye/Skin Contact.

Exposure limits: OSHA PEL .05 mg/cu m (Pb)
ACGIH TLV 2 mg/cu m (KOH)

Effects of Over-exposure:

Ingestion: The electrolyte could be harmful or fatal if swallowed.

Eye: The electrolyte is corrosive, eye contact could result in permanent loss of vision.

Dermal: The electrolyte is corrosive and skin contact will result in chemical burn.

Inhalation: Liquid inhalation is unlikely.

Signs/Symptoms of exposure: Contact with skin or eyes will cause a burning sensation and/or a soapy feeling for skin contact.

Emergency and First Aid procedures

Eye Contact: Flush with water for at least 15 minutes and get immediate medical attention.

Skin Contact: Wash affected area with plenty of water and remove contaminated clothing. If burning persists seek medical attention.

Ingestion: Give plenty of cold water - do not induce vomiting, get medical attention.

Handling Information:

Handling precautions: The Oxygen sensors are sealed and under normal circumstances the contents of the sensors do not present a health hazard. The following information is given as a guide in the event that a cell leaks.

Protective clothing: Rubber gloves, chemical splash goggles.

Clean-up procedure: Wipe down the area several times with a wet paper towel. Use a fresh towel each time.

Protective measures during cell replacement: Before opening the bag containing the cell, check the cell for leakage. If the cell leaks do not open the bag. If there is liquid around the cell while in the instrument put on gloves and eye protection before removing the cell.

Disposal: Should be in accordance with all applicable state, local or federal regulations.

Routine Maintenance

Routine maintenance of the Infant Flow™ Driver is limited to monthly checking of the Oxygen analyser calibration and periodic (4 monthly) checking of the calibration of the Air/Oxygen Mixer and Electronic Pressure Manometer, status of the gas inlet filters, integrity of the alarm systems and cleaning of the exterior surfaces.

An Infant Flow™ Driver in need of re-calibration, service or repair must not be used until the necessary procedures are performed and the equipment has been tested to ascertain that it is functioning correctly.

The full EME Model M672B Mk II Infant Flow™ Driver Service Manual (Part No 672-819) is available to qualified technicians to effect calibration, service and repair. If this is not feasible contact EME or an authorised distributor to insure full reliability and safety as special tools and equipment are required.

Routine maintenance as defined in this manual may be accomplished by competent individuals having experience in the maintenance or repair of devices of this nature. Parts designated in this manual should be replaced only with parts manufactured or sold by EME (Electro Medical Equipment) Ltd.

Gas Inlet Filters - There are three gas inlet filters, two on the Air inlet and one on the Oxygen inlet. These must be replaced periodically. We recommend that this is done annually unless the Infant Flow™ Driver is being powered by a portable air compressor. If this is the case it is recommended that the Air filters are changed at least every four months.

The exterior air filter can be observed through the polycarbonate bowl. If it is discoloured or wet it should be replaced.

The internal filters are sintered stainless steel. These should be changed annually or more frequently if there are signs of contamination. It is recommended that the O-ring seal and spring are changed at the same time as the filter. These are available as a kit under Part No S3522K.

CAUTION

The precision gas mixing device incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.

CAUTION

The precision gas mixing device incorporated in this product may become non-functional or damaged if used without the protective water trap and filters provided.

Changing the Oxygen Sensor

The Oxygen Sensor must be changed annually or when calibration is no longer possible. The sensor is located in the mechanical section of the Infant Flow™ Driver immediately behind the flowmeter. To gain access to this it is necessary to remove the top cover of the enclosure. This is achieved by removing the four M3 x 6mm instrument head screws (2 on each side), the top cover can be lifted off. Remove the four M3 x 8mm pan head screws on the rear cover and the remaining two M3 x 6mm instrument head screws on the electronic module. The module can now be slid forward to facilitate easy removal of the Oxygen Sensor. Carefully remove the electrical connector from the old cell by using a small blade screwdriver to release the locking clip and unscrew the Oxygen sensor from the flowmeter mounting block. Re-order part number is MR22.

The new Oxygen Sensor must be carefully screwed into the block, ensure that the O-ring is fitted before screwing in. Fit the electrical connector into the new Sensor observing the polarity. Re-assemble the Infant Flow™ Driver and switch on the power. Allow two hours for the Oxygen Sensor to stabilise before performing the full two point calibration. Return the Infant Flow™ Driver for use with patients only after calibration is satisfactory.

Galvanic Oxygen Fuel Cells tend to drift for the first few days and it is recommended that the calibration is checked daily for the first three days after a new Sensor is fitted.

Cleaning

The exterior surfaces of the Infant Flow™ Driver can be cleaned with a mild soap or liquid disinfectant solution. Do not use cleaning agents that contain abrasives.

CAUTION

Do not immerse any part of this device or gas or steam sterilise it. Damage will result.

Section 8

Electrical and Electronic description

Four circuit boards comprise the Infant Flow™ Driver electronics. These are the power supply board, the display board, the processor board and the mixer monitor board.

The Power Supply board is mounted on the side of the case adjacent to the mains input module. The board contains the mains transformer, T1, which has two primary windings so that they may be connected in series or parallel to suit a range of input voltage conditions. The transformer is protected by a non-resetting thermal fuse. The mains input is taken from the combined IEC connector, filter, mains switch, dual fuse carrier and voltage selector to the PCB flying leads. Voltage selection is made by lifting a flap under the fuseholder and sliding the tray out. The voltage selector may then be withdrawn and refitted as required to suit the mains voltage available. Four settings are provided, these are 100V, 120V, 220V and 240V.

The transformer has four secondary windings which are connected in two pairs to provide the inputs to the two bridge rectifiers BR1 for the + 5 VDC rail and BR2 for the ± 15 VDC rails. In series with each of the secondary windings is a fuse. Fuses F3 and F4 (both 1 Amp) are for the + 5 VDC rail and fuses F5 and F6 (both 250 mA) are for the ± 15 VDC rails. The transformer secondary windings for the + 5 VDC supply are connected in parallel to increase the current available. C3 is the reservoir capacitor for the + 5 VDC regulator, REG 3 a LM309K, which is mounted on the side panel behind the power supply board. REG 3 is connected to the power supply board with flying leads.

The transformer secondary windings for the ± 15 VDC supplies are connected in series with a centre tap to ground. The other two connections are used to supply the AC inputs of BR2 and produce raw DC voltages which are referenced to 0 V. The positive output of BR2 supplies REG1 via reservoir capacitor C1 and the negative output supplies REG2 via reservoir capacitor C2. The regulator pins are bypassed with ceramic capacitors to improve their transient response and all the power supply rails are fitted with discharge resistors to ensure that they are safe when the power is turned off or disconnected.

Power is conveyed from the power supply by a cable with a five way power connector at each end. This connects to the CON2 on the processor board. The display board receives its power via the forty way connector, CON1, from the processor board.

The display and processor board are mounted as a pair on the front panel. The signals to the display board are routed through the 40 way connector CON1. The pressure bar graph, D13 to D26 and the "Alarms Armed" LEDs D18, are driven by IC3, a MM5450N LED driver. The alarm LEDs, D11, D27, D2 and D5 are driven by IC2, a UCN5812A. The seven segment Oxygen concentration displays, LD1 to LD3, are driven by IC1, an ICM7212AMIPL display driver. Also fitted on the display board is the "ARM/MUTE" push button, SW1, and a NORP12 light dependant resistor, LDR1, for the auto-dimming of the displays. The luminous intensity for the displays is controlled by a signal derived from LDR1. The two display drivers require different signals to change the brightness of the displays so two op-amp circuits are provided on the processor board.

The processor board fits behind the display board and is connected to it by a 40 way connector, CON1. The instrument is based around a Motorola MC68705R3P micro-controller, IC1. This device is one time programmable and, should it become defective, can only be replaced with a pre-programmed device obtained from EME or an authorised distributor.

The micro-controller contains the following elements:

6805 Micro Computer
24 Bi-Directional I/O Lines
8 Input Only Lines
8 Channel Analogue To Digital Converter
3776 Byte Programmable Read Only Memory
112 Byte Random Access Memory
8 Bit Timer
7 Bit Pre-Scaler
Memory Mapped I/O

The Micro-processor clock signal is generated by XTL1 and C2, a 4 MHz external crystal and capacitor. There is no provision for adjusting the frequency of the oscillation.

The pressure sensor PT1, is a Sensym/EME solid state device having a range of 0 to 1 PSI which is fitted directly to the processor board. It can withstand up to 20 PSI without sustaining damage. This item is not a standard component as it is specially selected to our specification for low noise and zero temperature drift at zero. It must only be replaced with a device to the same specification obtained from EME or an authorised distributor.

The reference section of the LM10, IC7, produces 200 mV which is amplified by the op-amp section of IC7 to produce 12 V to energise the pressure sensor. The AMP02, IC6, provides the signal conditioning for the pressure sensor with potentiometer VR3 being used to adjust the stage gain. Stage 1 of IC5, a LM324, is used in conjunction with VR7 to swing the output of the APM02 so that any offset can be trimmed out. The amplified output from the pressure sensor circuit is applied to the analogue input AN0 of the micro-controller. In parallel with this signal is IC4, an SGS Thomson L9700 or Texas Instruments TL7726 precision clamp. This ensures that the inputs to the micro-controller cannot go outside the limits of the ADC reference.

Input AN1 on IC1 is used for the signal conditioned mixer monitor potentiometer. This potentiometer is connected between 0V and 5V and feeds an output of a proportion of this depending upon where the mixer shaft is set. Stage 1 of IC8, an LM324 quad op-amp, amplifies the signal and IC8 stage 2, provides an offset to ensure that the output achieves a level of 0.05V at 21% O_2 and 5V at 100% O_2. VR6 adjusts the offset and VR5 sets the span. This section of the electronics is used for determining the Oxygen alarm limits, IC4 is again used to clamp the signal to the micro-controller. Input AN2 on IC1 is used for the Oxygen monitor. IC8 stage 4 provides an offset to trim out any zero error from the Oxygen sensor, whilst stage 3 provides the necessary amplification. VR8 adjusts the offset and VR4 adjusts the gain. IC4 is used to clamp the signal. Input AN4 on IC1 is spare and is connected to ground to prevent noise pick-up from getting into the measurement circuitry.

The display brightness levels are generated from the NORP12 signal fed back from the Display Board. A resistive circuit, VR2 and R11, is used to set the overall brightness level and the fed-back signal modulates this. The brightness of the 7-segment displays is set by the difference between this level and 15V. The brightness of the LEDs is adjusted by using trimmer VR1 to set a constant current dependant upon the voltage at its wiper. IC5 stage 3 and transistor TR2 form a voltage controlled constant current source.

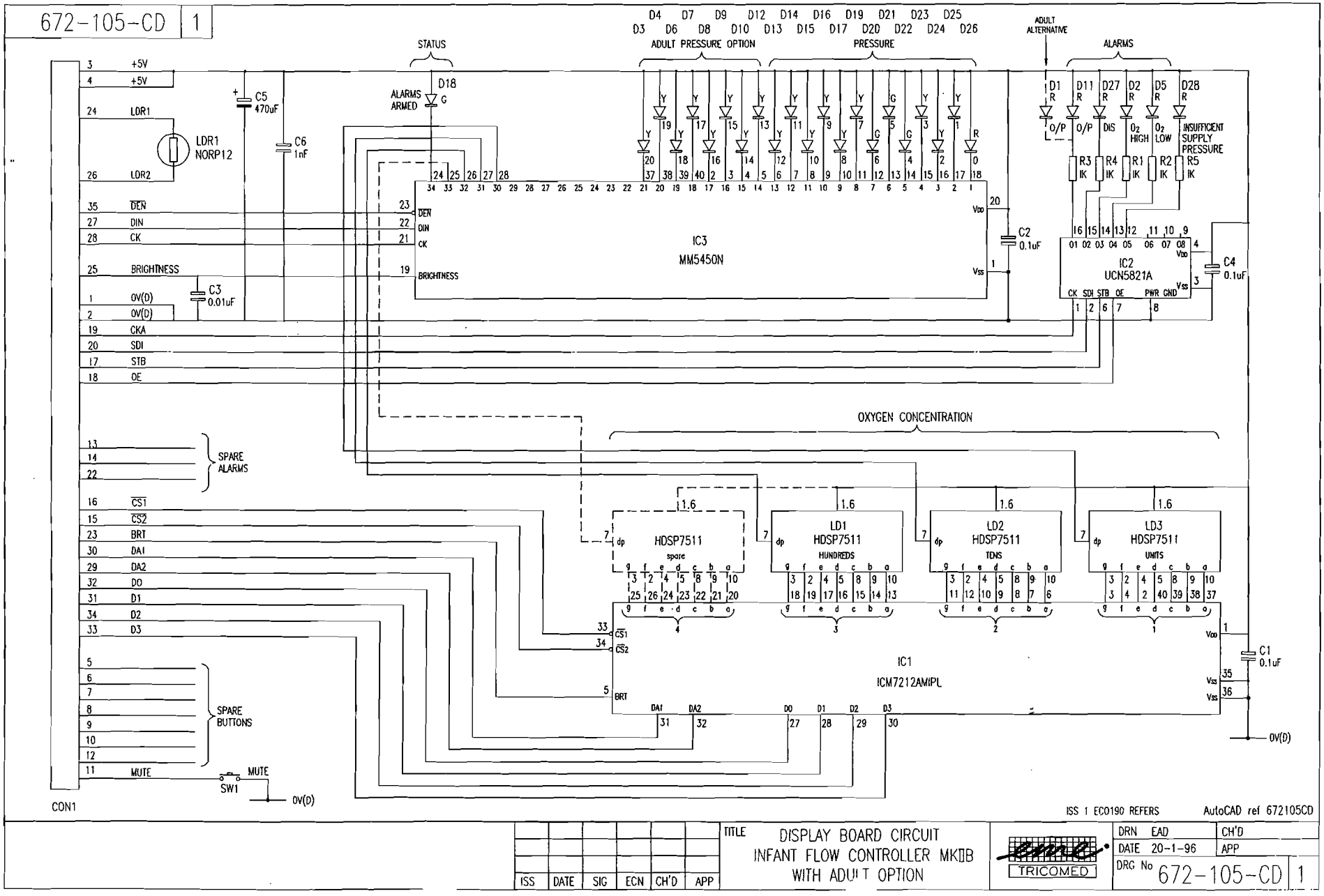
The audible alarm is fitted on the Processor Board and is driven by the micro-controller via MOSFET TR1. The audible alarm is powered from the +5V rail and is a high efficiency type, selected for its high output at low voltages.

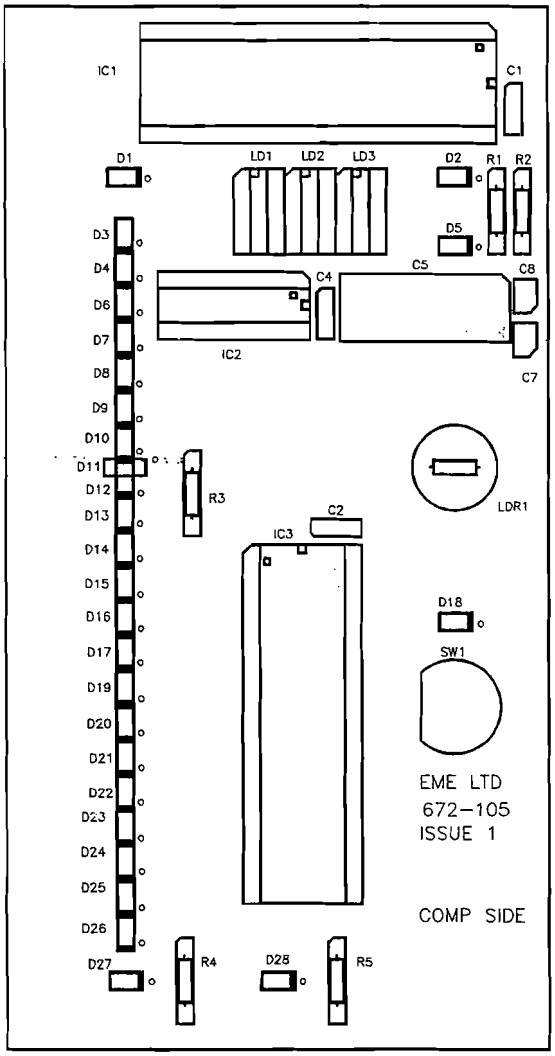
An over-pressure relief valve is fitted in the Infant Flow™ Driver to vent any excessive pressures to atmosphere. This slave over-pressure valve is driven by the micro-controller using a solenoid valve as a master. The power source for the solenoid valve is a three terminal regulator, REG1, connected as a constant current source. The solenoid valve is operated by a MOSFET, TR3, connected in series with opto-coupler, IC9, to monitor the functioning of the solenoid valve circuit.

Also fitted on the Processor Board is a two-stage watchdog circuit. The first stage, IC2, is a Silicon General SG3548N which has four sense inputs, an inverter and a threshold input. The inverter is connected so as to allow monitoring of the minus 15V power rail by Sense 4 input. The 5V and 15V power rails are monitored by Sense 2 and Sense 3 inputs respectively. The Sense inputs are checked for voltages both over and under the set levels. The tolerance on the over and under voltages is set by using the threshold input. The resistors, R6 and R8, set the window width to plus and minus 5%. The line input, which is normally used to monitor an ac input, is used here to gate the watchdog reset pulses from the micro-controller with the power supply monitor signal to produce the wired-and output at pins 7, 9 and 10. Whilst all is well, this pulsating signal is applied to IC3 pin 6 to prevent timing out of the watchdog. IC3 is a Maxim MAX694CPA, Supertex MP694P or an AMD AD694AN microprocessor supervisory circuit, of which only the 1.6 second timer is used. If any power rail goes above its permitted value, the O/V output at pin 9 will go low; if any power rail goes below its permitted value, the U/V output at pin 10 will go low. In either case, the watchdog reset pulses will be interrupted and the micro-controller will reset after 1.6 seconds delay. C12 provides a short delay on operation of the sense inputs to avoid operation on transients.

The mixer monitor is mounted on the panel of the mixer unit where it is used to monitor the controller shaft position.

Trouble Shooting Guide		
Problem or Fault	Possible cause	Rectification
The electronic module does not function at all	No mains power Power Supply faulty	Power cord connected? Mains switch turned on? Voltage Selector correctly set? Check primary fuses. Check plug fuse (if fitted) Power connector plugged in?
Electronic Module continually resetting	+ 5 VDC faulty + 15 VDC faulty - 15 VDC faulty	Check PSU secondary fuses Check BR1 and BR2 Bridge rectifiers Check Voltage regulators
All displays dim	Auto dimming circuit faulty or not set	Check VR1 Check VR2 Check LDR1 Check IC5
Audio alarm works but visual does not	Alarm LEDs defective	Check Alarm LEDs
Visual alarm works but audible does not	Bleeper faulty Bleeper driver faulty	Check bleeper Check ZVN4306A, TR3
Manometer display off	Faulty driver	Check MM5450N, IC2
Parts of Manometer display missing	Faulty driver or Faulty LEDs	Check MM5450N, IC2 Check LEDs
Oxygen display off	Faulty driver or Oxygen monitor disabled	Check ICM7212AMIPL, IC1 Check SW1 on processor board
Segments of Oxygen display missing	Faulty driver or Faulty display	Check ICM7212AMIPL, IC1 Check 7 segment display


672-105-CD 1
STATUS
ALARMS ARMED
D18
ADULT PRESSURE OPTION
PRESSURE
ADULT ALTERNATIVE
ALARMS
D1 R O/P
D11 R O/P
D27 R DIS
D2 R O2 HIGH
D5 R O2 LOW
D28 R INSUFFICIENT SUPPLY PRESSURE
R3 1K
R4 1K
R1 1K
R2 1K
R5 1K
+5V
+5V
LDR1
LDR2
LDR1 NORP12
C5 470uF
C6 1nF
C3 0.01uF
C2 0.1uF
C4 0.1uF
C1 0.1uF
IC3 MM5450N
IC2 UCN5821A
CK SDI STB OE PWR GND
DEN
DIN
CK
BRIGHTNESS
0V(D)
CKA
SDI
STB
OE
OXYGEN CONCENTRATION
SPARE ALARMS
CS1
CS2
BRT
DA1
DA2
DO
D1
D2
D3
SPARE BUTTONS
MUTE
SW1
CON1
LD1 HDSP7511 HUNDREDS
LD2 HDSP7511 TENS
LD3 HDSP7511 UNITS
HDSP7511 spare
IC1 ICM7212AMIPL
ISS 1 EC0190 REFERS
AutoCAD ref 672105CD
TITLE DISPLAY BOARD CIRCUIT INFANT FLOW CONTROLLER MKIIB WITH ADULT OPTION
TRICOMED
DRN EAD
CH'D
DATE 20-1-96
APP
DRG No 672-105-CD 1
ISS DATE SIG ECN CH'D APP



672105 PCB COMPONENT IDENTIFICATION

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
1	M672105	DISPLAY PRINTED CIRCUIT BOARD	1				
2							
3	EH20998	PIN HEADER 20 + 20 WAY STRAIGHT	1	CON1	HARWIN	M20-998 20 05	
4							
5							
6	EH10TP	IC SOCKET 10 PIN	3	LD1, LD2, LD3	SAMTEC	ICH-210-S-GT	
7							
8	BPKEYS	SWITCH PUSHBUTTON	1	SW1			
9	EC470/10	CAPACITOR 470uF 10V AX ELEC	1	C5	PANASONIC	ECEB1AU471	
10	EC.1/100C	CAPACITOR 0.1uF 100V CER	3	C1,C2,C4			
11	EC.01/63	CAPACITOR 0.01uF 63V POLYESTER	1	C3	WIMA	MKS02-0.01uf-63V	
12	EC1000/100,	CAPACITOR 1nF 100V CER	1	C6	AVX-KYOCERA	SR151C102KTA	
13	ERLD12	LIGHT DEPENDANT RESISTOR	1	LDR1	SILONIX	NORP12	
14							
15	ER1K	RESISTOR 1K	4	R1,R2,R3,R4			
16							
17	ED7511	7-SEGMENT DISPLAY, HE RED	3	LD1,LD2,LD3	HEWLETT-PACKARD	HDSP7511 BRIGHTNESS CLASSIFICATION D	⚠2
18							
19	ED57123	LED RED HE 5mm x 2mm	5	D2,D5,D11,D26,D27			
20	ED53123	LED YELLOW 5mm x 2mm	9	D13-17,D19,D23-25			
21	ED54123	LED GREEN HE 5mm x 2mm INTENSITY MATCHED	4	D18,D20-22	QUALITY TECH or KINGBRIGHT	MV54123 or L113-LGDT	
22							
23	ES5450	LED DRIVER MM5450N	1	IC3	NAT. SEMICONDUCTOR	MM5450N	
24	ES7212	DISPLAY DRIVER ICM7212AMIPL	1	IC1	HARRIS (INTERSIL)	ICM7212AMIPL	
25	ES5821	LATCH DRIVER 8 BIT	1	IC2	ALLEGRO	UCN5821A	

ISS	DATE	SIG	ECO	CH'D	APP
2			219		

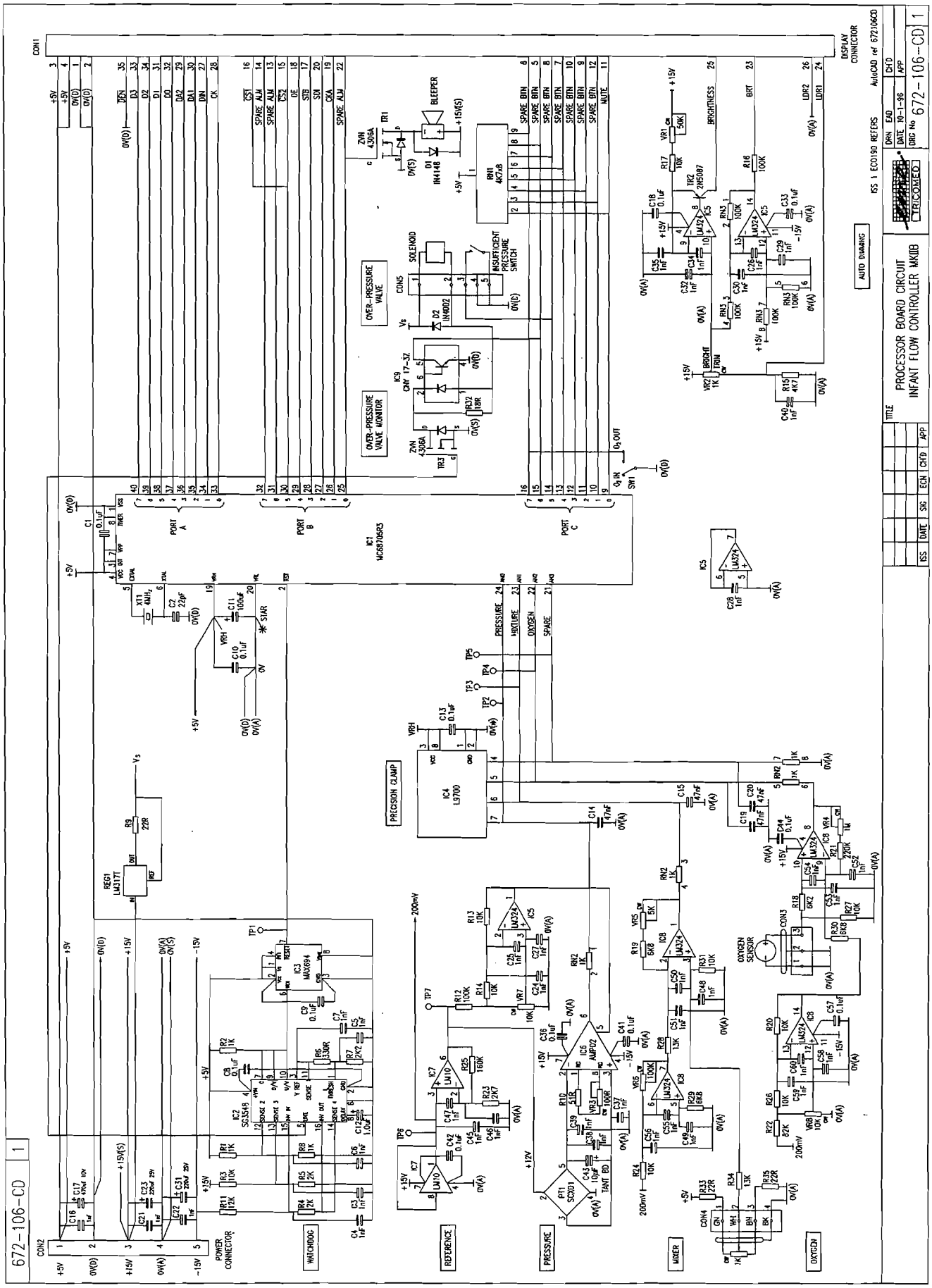
TITLE

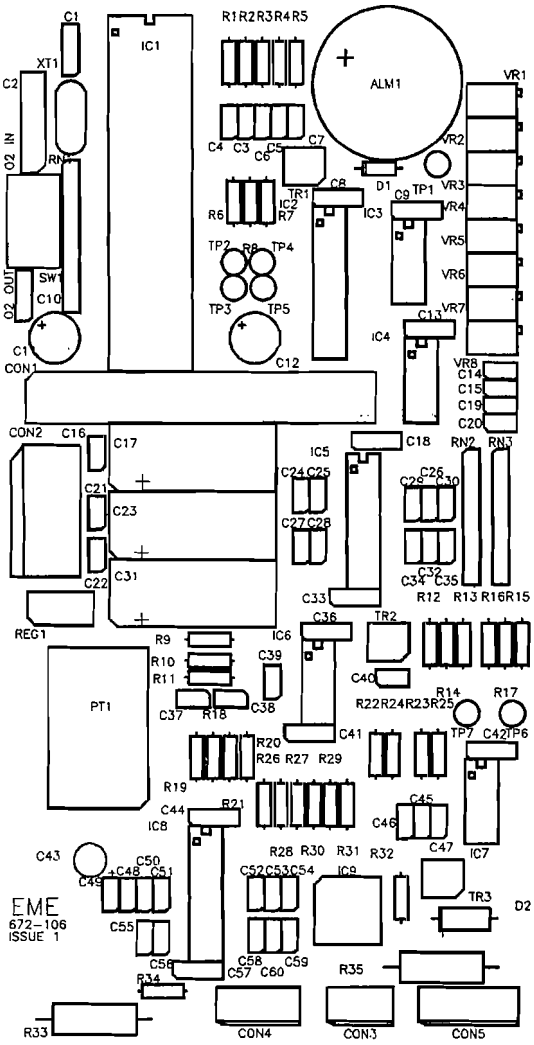
INFANT FLOW DRIVER Mk 2B
DISPLAY PCB ASSY

EME 200-006

TRICOMED

DRN	EAD	CH'D	RJS
DATE	18-11-95	APP	PDH
PARTS LIST No	672-105-PL	SHT 1 of 1 SHTS	2


672-106-CD 1
PROCESSOR BOARD CIRCUIT
INFANT FLOW CONTROLLER MKIIB
DRG No 672-106-CD 1
AUTO DRAWING
DISPLAY CONNECTOR
POWER CONNECTOR
WATCHDOG
REFERENCE
PRESSURE
MIXER
OXYGEN
PRECISION CLAMP
OVER-PRESSURE VALVE
OVER-PRESSURE VALVE MONITOR
INSUFFICIENT PRESSURE SWITCH
SOLENOID
BLEEPER
BRIGHTNESS
OXYGEN SENSOR



672106 PCB COMPONENT IDENTIFICATION

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
1	M672106	PROCESSOR PCB	1				
2							
3							
4	EH40TP	IC SOCKET 40 PIN	1	IC1			
5	EH20983	SOCKET 20 + 20 WAY STRAIGHT	1	CON 1	HARWIN	M20-983 20 22	
6	EH5W	5 WAY STRAIGHT HEADER	1	CON 2	TAKBRO (JST)	B5P-VH	
7	EH5PIN	BASE POST 5 WAY	1	CON 5	TAKBRO (JST)	B5B-XH-A	
8	EH3PIN	BASE POST 3 WAY	1	CON 3	TAKBRO (JST)	B3B-XH-A	
9	EH4PIN	BASE POST 4 WAY	1	CON 4	TAKBRO (JST)	B4B-XH-A	
10	EHTPW	TEST PIN	7	TP1-TP7	WILLLIAM HUGHES	TYPE 101 WHITE	
11							
12	EC470/10	CAPACITOR 470uF 10V AXIAL EL	1	C17			
13	EC220/25A	CAPACITOR 220uF 25V AXIAL EL	2	C23,C31	PANASONIC	ECEB1EU221	
14	EC100/6.3T	CAPACITOR 100uF 6.3V TANT BEAD	1	C11			
15	EC1/35	CAPACITOR 1uF 35V TANT BEAD	1	C12			
16	EC10/16	CAPACITOR 10uF 16V TANT BEAD	1	C43	THOMSON	FB070D106MHB	
17	EC.1/100C	CAPACITOR 0.1uF 100V CERAMIC	12	C1,8-10,13,18,33,36,41,42,44,57			
18	EC.047/63	CAPACITOR 47nF 63V POLYESTER	4	C14,C15,C19,C20	WIMA	MKS02-0.047-63V	
19	EC22/160	CAPACITOR 22pF 160V POLYSTYRENE	1	C2			
20	EC1000/100	CAPACITOR 1nF 100V CERAMIC	37	C3-7,16,21,22,24-30,32	AVX-KYOCERA	SR151C102KTA	
				34,35,37-40,45-56,58-60			
21							
22							
23	EP100RRAS	POTENTIOMETER 25 TURN 100R 1/4in	1	VR3	BOURNS	3266X-1-101	
24	EP1KRAS	POTENTIOMETER 25 TURN 1K 1/4in	1	VR2	BOURNS	3266X-1-102	
25	EP5KRAS	POTENTIOMETER 25 TURN 5K 1/4in	1	VR5	BOURNS	3266X-1-502	
26	EP10KRAS	POTENTIOMETER 25 TURN 10K 1/4in	2	VR7,VR8	BOURNS	3266X-1-103	
27	EP50KRAS	POTENTIOMETER 25 TURN 50K 1/4in	1	VR1	BOURNS	3266X-1-503	

ISS	DATE	SIG	ECO	CH'D	APP
2			219		

TITLE

INFANT FLOW DRIVER MK 2B
PROCESSOR PCB ASSY

EME 200-006

TRICOMED

DRN EAD | CH'D RJS
DATE 20-11-95 | APP PDH

PARTS LIST No 672-106-PL | SHT 1 of 3 SHTS | 2

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
29	EP100KRAS	POTENTIOMETER 25 TURN 100K 1/4in	1	VR6	BOURNS	3266X-1-104	
30	EP1MRAS	POTENTIOMETER 25 TURN 1M 1/4in	1	VR4	SPECTROL (BOURNS)	TYPE 74 1M (3266X-1-105)	△2
31	ER22R1W	RESISTOR 22R 2% 1W FLAMEPROOF	2	R33,R35	VISHAY	FP1 22R 2%	
32	ER22R	RESISTOR 22R 2%	1	R9			
33	ER51R	RESISTOR 51R 1%	1	R10	PHILIPS	MRS25 1% 51R 50ppm	
34	ER330R	RESISTOR 330R 1%	1	R6	PHILIPS	MRS25 1% 330R 50ppm	
35	ER1K	RESISTOR 1K 2%	3	R1,R2,R8			
36	ER2K	RESISTOR 2K 1%	2	R4,R5	PHILIPS	MRS25 1% 2K 50ppm	
37	ER2K2	RESISTOR 2K2 2%	1	R7			
38	ER2K7	RESISTOR 2K7 1%	1	R23	PHILIPS	MRS25 1% 2K7 50ppm	
39	ER4K7	RESISTOR 4K7 2%	1	R15			
40	ER6K2	RESISTOR 6K2 2%	1	R18			
41	ER6K8	RESISTOR 6K8 2%	3	R19,R29,R30			
42	ER10K	RESISTOR 10K 2%	9	R3,13,14,17,20,24,26,27,31			
43	ER12K	RESISTOR 12K 2%	1	R11			
44	ER13K	RESISTOR 13K 2%	2	R28.R34			
45	ER100K	RESISTOR 100K 2%	2	R12,R16			
46	ER82K	RESISTOR 82K 1%	1	R22			
47	ER160K	RESISTOR 160K 2%	1	R25			
48	ER220K	RESISTOR 220K 2%	1	R21			
49	ER18R	RESISTOR 18R 2%	1	R32			NOT FITTED
50	ERN1KX4	RESISTOR NETWORK 1K x 4 ISOLATED	1	RN2	BECKMAN (BOURNS)	L08-3C102/G (4608X-102-1K)	
51	ERN4K7	RESISTOR NETWORK 4K7 x 8	1	RN1			
52	ERN100KX4	RESISTOR NETWORK 100K x 4 ISOLATED	1	RN3	BECKMAN (BOURNS)	L08-3C104/G (4608X-102-100K)	
53							
54	EH4000	CRYSTAL 4MHz	1	XT1			
55	ED4148	SIGNAL DIODE IN4148	1	D1			
56	ED4002	RECTIFIER DIODE IN4002	1	D2			

ISS	DATE	SIG	ECN	CH'D	APP
2			219		

TITLE

INFANT FLOW DRIVER MK 2B
PROCESSOR PCB ASSY

EME 200-006

TRICOMED

DRN	EAD	CH'D	RJS
DATE	20-11-95	APP	PDH

PARTS LIST No 672-106-PL

SHT 2 of 3 SHTS

2

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
57	ET5087	TRANSISTOR PNP LOW NOISE	1	TR2	NAT SEMICONDUCTORS	2N5087	
58	ET4306	TRANSISTOR N-CHANNEL DMOS	2	TR1,TR3	ZETEX	ZVN4306A	
59	EH519-960	TRANSISTOR MOUNTING PAD	3	TR1,TR2,TR3	MMX (MEC)	MS923-25 (MPX-02)	2
60	EV317T	REGULATOR ADJUSTABLE 1.5A	1	REG1	NAT SEMICONDUCTORS	LM317T	
61							
62	EHSM4L	AUDIBLE ALARM	1	ALM1	SONITRON	SM4BL/SMA-21L	
63							
64	ES68705	MICRO CONTROLLER PROGRAMMED	1	IC1	MOTOROLA	MC68705R3P or CP or S or CS	
65	ES3548	QUAD POWER FAULT MONITOR	1	IC2	LINFINITY	SG3548N	
66	ES694	MICRO PROCESSOR SUPERVISOR	1	IC3	MAXIM,SUPERTEX or ANA DEV	MAX694CPA, MP694P or ADM694AN	
67	ES10	OP-AMP AND REFERENCE	1	IC7	NAT SEMICONDUCTORS	LM10CN	
68	ES02	INSTRUMENTATION AMPLIFIER	1	IC6	PMI	AMP-02	
69	ES324	QUAD OP--AMP	2	IC5,IC8			
70 71	ES9700 or ES7726	HEX PRECISION CLAMP	1	IC4	SGS-THOMPSON TEXAS	L9700 TL7726CP	
72	ESCNY17	OPTO-ISOLATOR	1	IC9	QUALITY TECHNOLOGY	CNY17-3Z	
73							
74	APM1801	PRESSURE TRANSDUCER 0-1 PSI	1	PT1			
75	M641009	TUBE PRESSURE TRANSDUCER	1				PT1
76							
77	F3201	SCREW PAN HD M3 x 20 LG SS	2				PT1
78	F3NN	NUT NYLOC M3	2				PT1
79							
80	EH334-224	SWITCH SLIDE SPDT	1	SW1	MORS or EATON or	25136NLDH or D12ES or	
					NDK NISSHO ELECTRIC	US1D-1	

ISS	DATE	SIG	ECO	CH'D	APP
2			219		

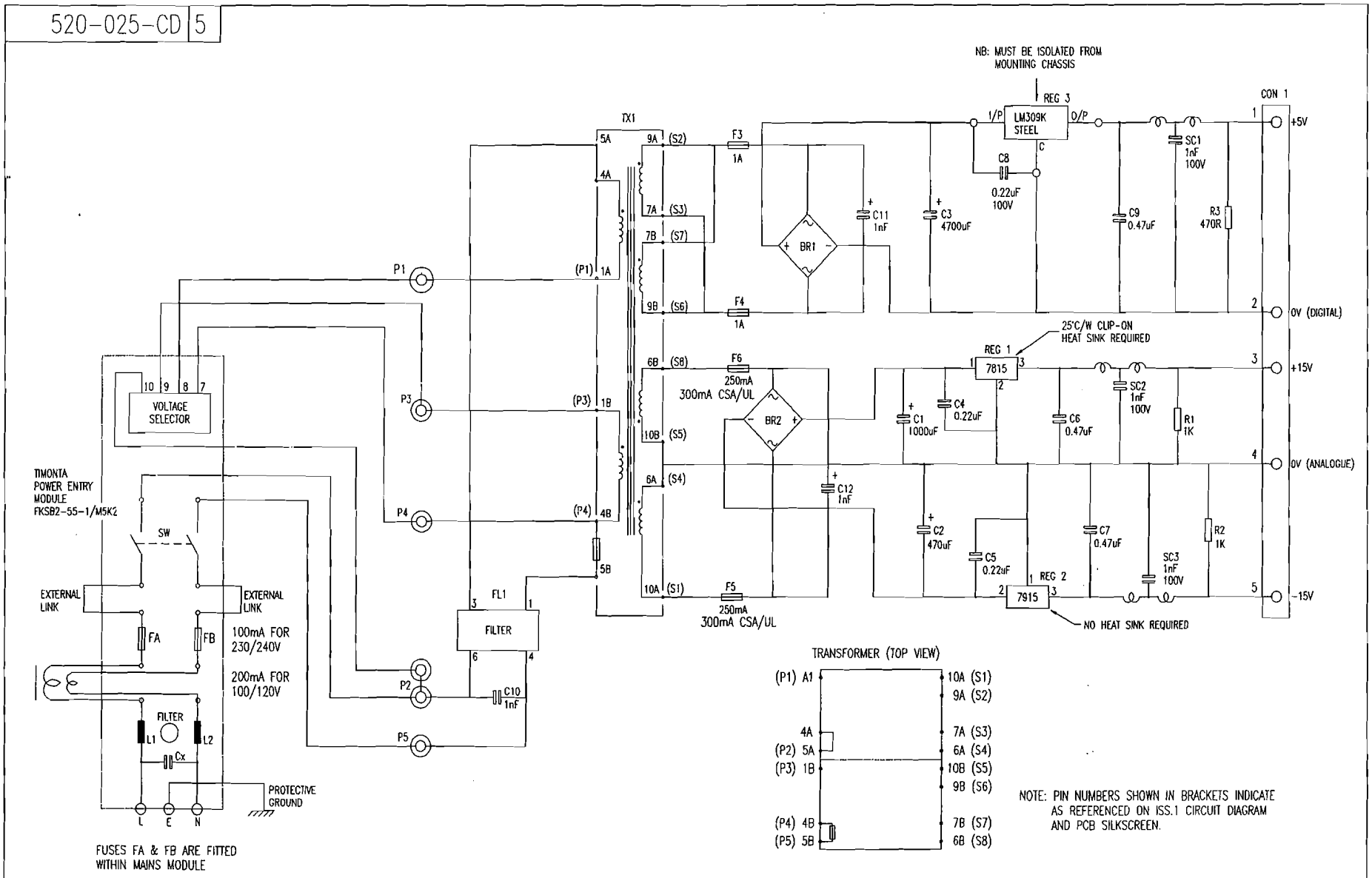
TITLE

INFANT FLOW DRIVER MK 2B
PROCESSOR PCB ASSY

EME 200-006

TRICOMED

DRN EAD	CH'D RJS
DATE 20-11-95	APP PDH
PARTS LIST No 672-106-PL	SHT 3 of 3 SHTS 2



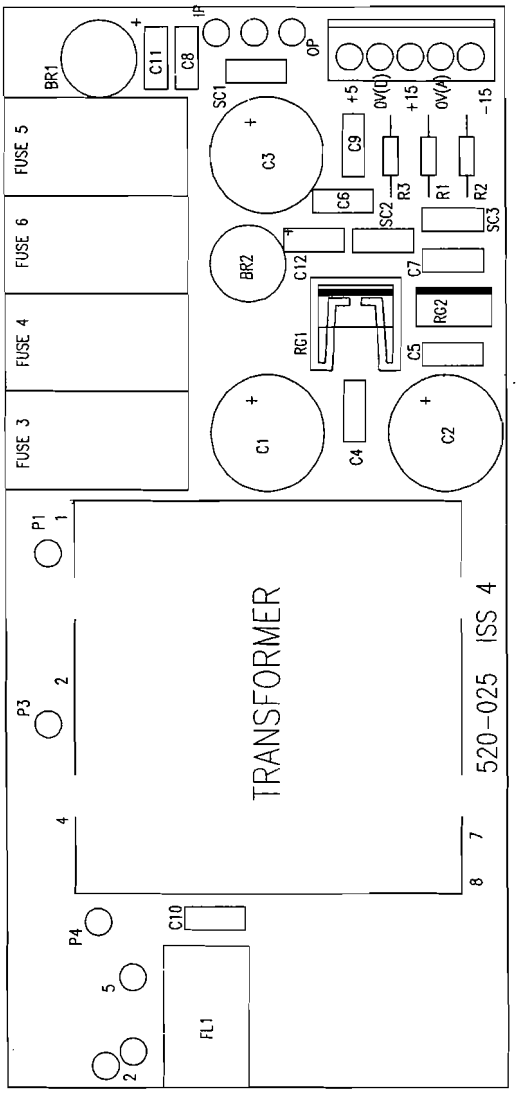
ISS	DATE	SIG	ECO	CH'D	APP
5			224		
4	28/5/96	EAD	190	RJS	PDH

ISS 5 ECO224
CONN1 PIN NUMBERS ADDED
FILTER REF (FL1) ADDED

TITLE
NEW PSU CIRCUIT DIAGRAM
IFD Mk2R

TRICOMED

DRN	EAD	CH'D	RJS
DATE	04-01-95	APP	PDH
DRG No	520-025-CD		5



520025 PCB COMPONENT IDENTIFICATION

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
1	M520025	POWER SUPPLY PCB (ISSUE 4)	1				6
2	APM6384	TRANSFORMER (520-048/051 = TRANS SPEC)	1	TX1	TAYLOR & GOODMAN		
3	EC1000/25R	CAPACITOR 1000uF 25V RAD EL	1	C1	NIPPON CHEMI-CON (PANASONIC)	SXEVB1000/25M (ECA1EFG102)	
4	EC470/40	CAPACITOR 470uF 40V RAD EL	1	C2	RUBYCON	63TWSS470	6
5	EC4700/16	CAPACITOR 4700uF 16V RAD EL	1	C3	NIPPON CHEMI-CON	SM16VB4700MC	
6	EC.22/100	CAPACITOR 0.22uF 100V CER	3	C4,C5,C8	PHILIPS	CZ30A 224M	
7	EC.47/100	CAPACITOR 0.47uF 100V CER	3	C6,C7,C9	PHILIPS	CZ30A 474M	
8	EC1000/250AC	CAPACITOR 1nF 250V AC CER	3	C10,C11,C12	RODERSTEIN	WY0102MCMBF0K	6
9	EC3T1000/100	CAPACITOR 3-TERMINAL 1nF 100V	3	SC1-SC3	MURATA	DSS306-55Y5S102-M100	
10							
11	APM4000	FILTER (520-035 SPECIFICATION)	1	FL1	TAYLOR AND GOODMAN		
12	ER470R	RESISTOR 470R 2%	1	R3			
13	ER1K	RESISTOR 1K 2%	2	R1,R2			
14	ED1AB	BRIDGE RECTIFIER 1A	2	BR1,BR2	GEN INSTRUMENTS	W02M	
15	EV7815	REGULATOR 15V 1A	1	REG1	NAT SEMICONDUCTORS	LM7815CT	
16	EV7915	REGULATOR -15V 1A	1	REG2	NAT SEMICONDUCTORS	LM7915CT	
17							
18	EH23432	FUSEHOLDER PCB MTG (HORIZONTAL)	4	F3,F4,F5,F6	SCHURTER	FAX 031 3531	
19	EF1AMP	FUSE 1A ANTISURGE (20 x 5)	2	F3,F4	BESWICK	S502 1A	
20	EF250MA	FUSE 250mA ANTISURGE (20 x 5)	2	F5,F6	BESWICK	S502 250mA	
21	EH232944	HEATSINK TO220 CLIP ON 25 DEG C/W	1	REG1			
22							
23	EH5W	5 WAY STRAIGHT HEADER	1	CON 1	TAKBRO	JST B5P-VH	
24							
25	EF300MA/S	FUSE 300mA SLOW BLOW (20 x 5)	2	F5,F6	BEL	5TT300	UL/CSA ALT TO ITEM 20
26	EF1AMP/S	FUSE 1A SLOW BLOW (20 x 5)	2	F3,F4	BEL	5TT1	UL/CSA ALT TO ITEM 19
27							
28							

ISS	DATE	SIG	ECO	CH'D	APP
6			224		
5	28/6/96	EAD	190	RJS	PDH

TITLE: NEW POWER SUPPLY PCB ASSY FOR IFD MK2B

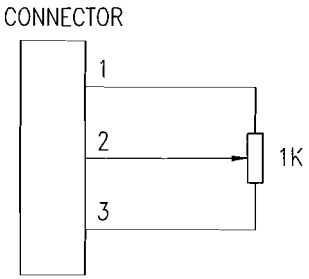
EME 200-006

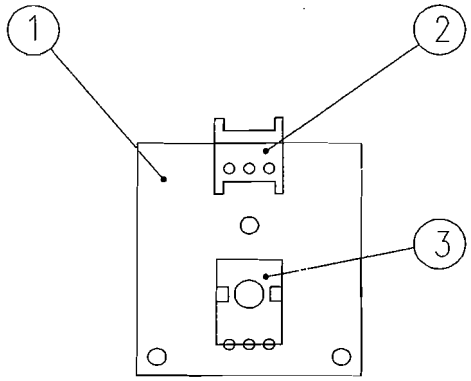
TRICOMED

DRN EAD	CH'D RFJ
DATE 03-01-95	APP PDH
PARTS LIST No 520-025-PL	SHT 1 of 1 SHTS

6

672-007-BA/CD | 1





AutoCAD ref 672007BC

ISS	DATE	SIG	ECN	CH'D	APP

TITLE

MIXER MONITOR PCB ASSY/CD
INFANT FLOW DRIVER Mk2

TRICOMED

DRN	EAD	CH'D	
DATE	20-05-94	APP	
DRG No	672-007-BA/CD		1

ITEM	STOCK No	DESCRIPTION	QTY	COMP REF	MANUFACTURER	MANUFACTURER PART No	REMARKS
1	M672007	MIXER MONITOR PCB	1				
2							
3							
4							
5	EP1KW	POT 1K PC MOUNTING W/O SHAFT	1		MEGGITT ELECTRONICS	MEC CITEC TYPE 51 1K LINEAR	
6							
7	EH3PRA	3 WAY BASE POST R/ANGLE 2.5mm	1		TAKBRO (JST)	S3B-XH-A	

ISS	DATE	SIG	ECN	CH'D	APP

TITLE

INFANT FLOW DRIVER MK 2
MIXER MONITOR PCB ASSY

EME 200-006

TRICOMED

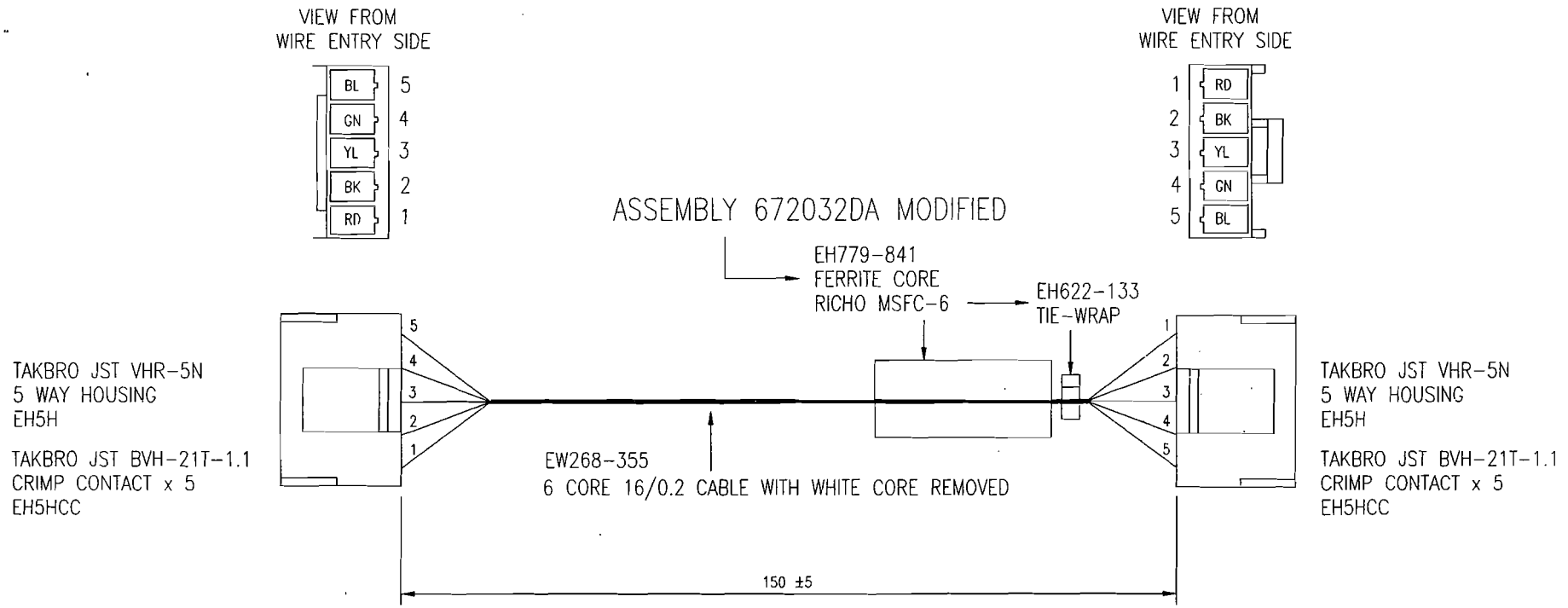
DRN	EAD	CH'D	RJS
DATE	20-05-94	APP	PDH

PARTS LIST No 672-007-PL

SHT 1 of 1 SHTS

2

672-132-DA | 1



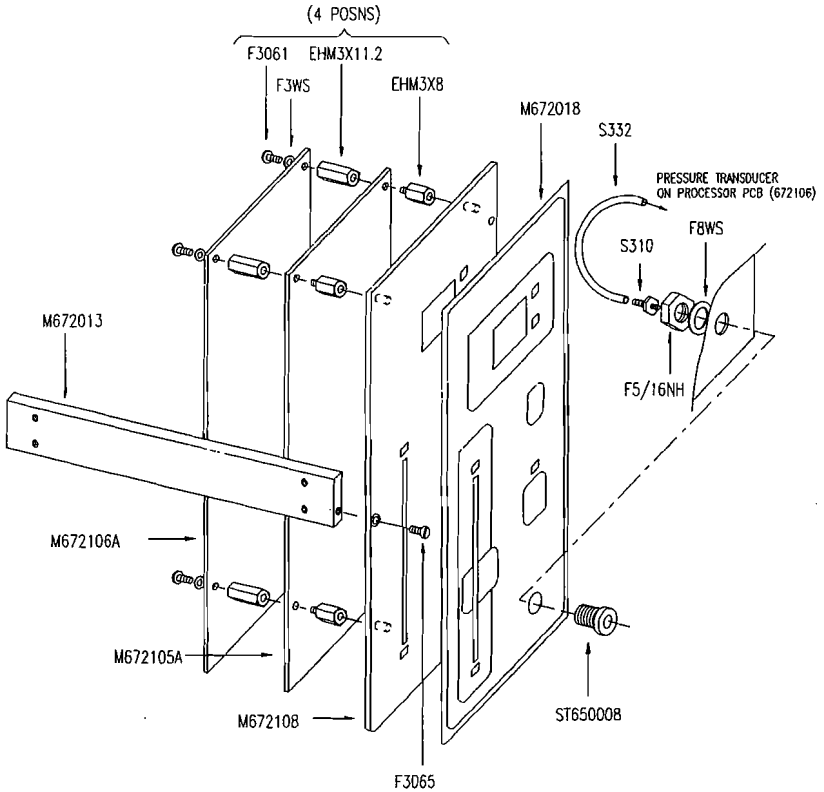
ISS	DATE	SIG	ECN	CH'D	APP

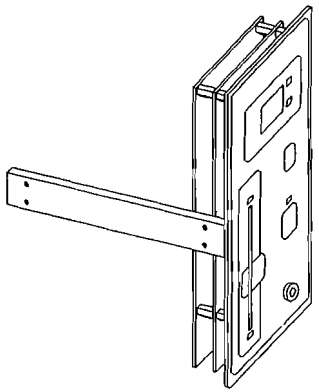
TITLE INTERCONNECTION BETWEEN POWER SUPPLY PCB AND PROCESSOR PCB ASSEMBLY 672032DA MODIFIED IFD Mk2B

TRICOMED

DRN EAD	CH'D RJS
DATE 14-11-95	APP PDH
DRG No 672-132-DA	1

672-108-SA | 2





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TITLE
FRONT PANEL (LH) SUB ASSY
INFANT FLOW VER Mk2B

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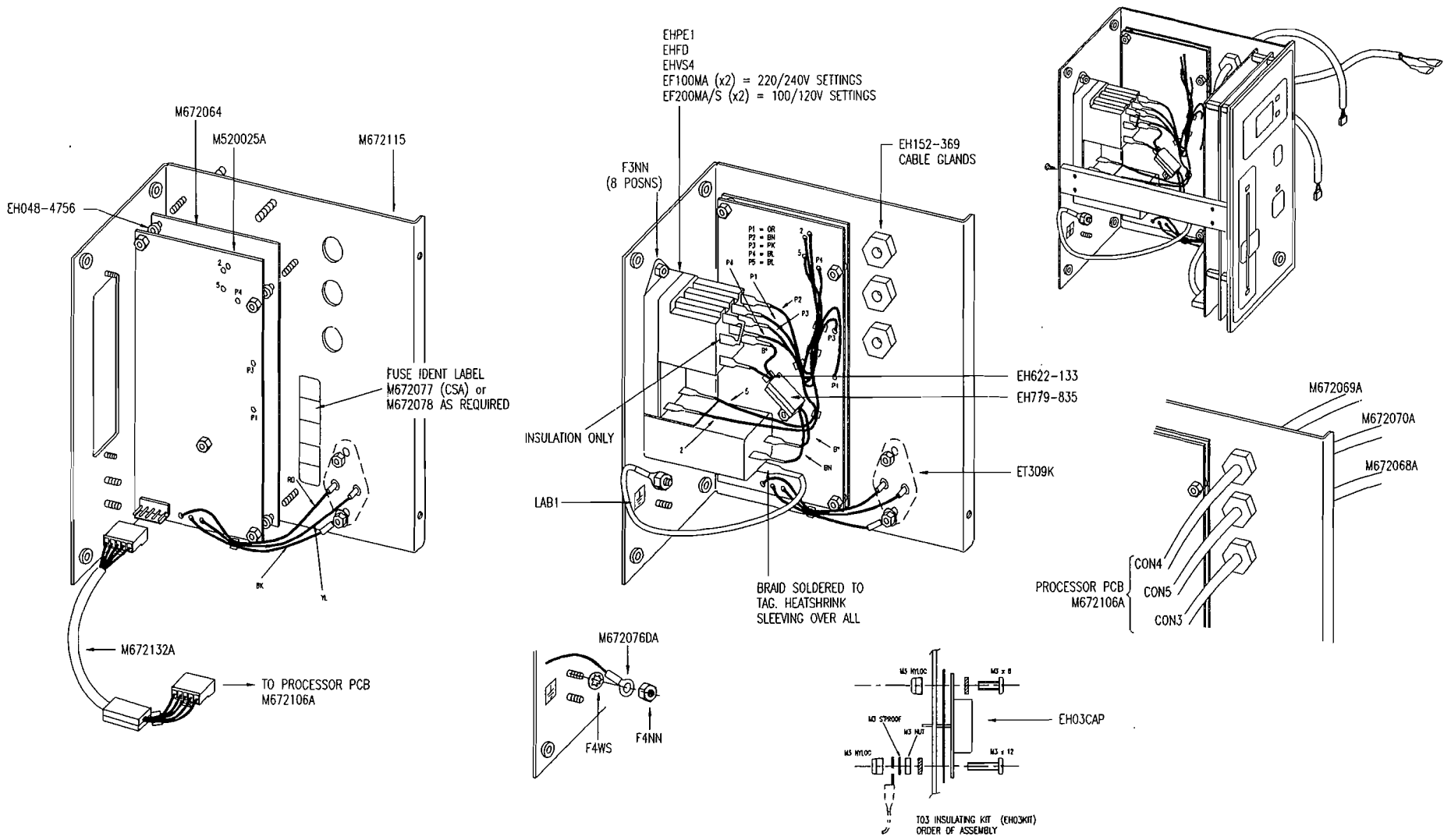

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INFANT FLOW DRIVER Mk2B

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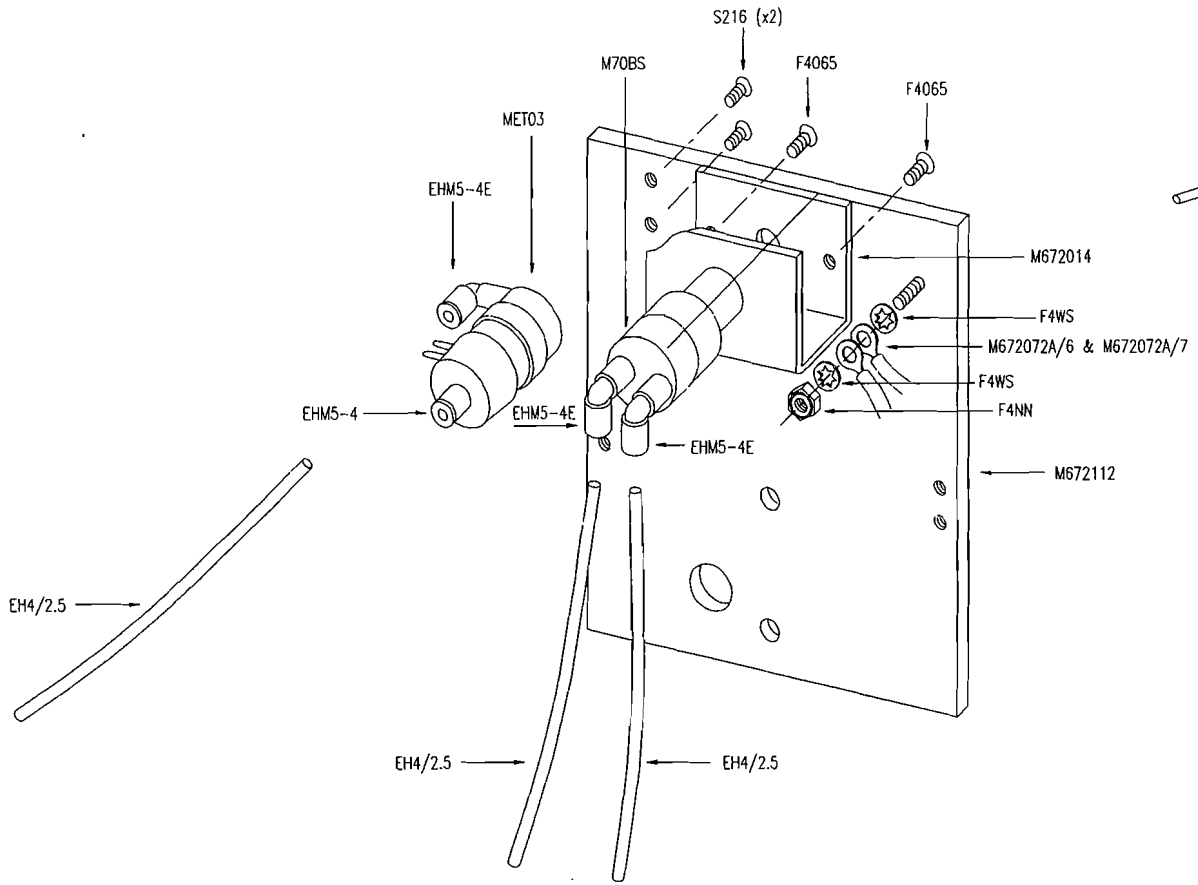

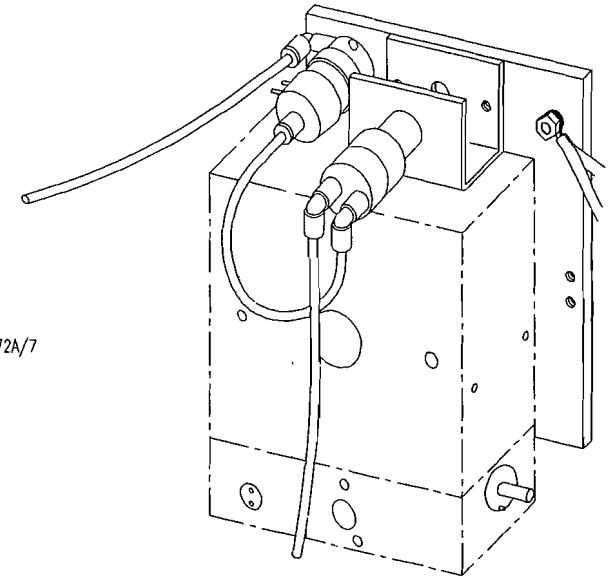

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TITLE
SPACER PLATE ASSEMBLY
INFANT FLOW DRIVER Mk2B

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DATE 27-11-95	APP PDH
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Section 9

Electronic Calibration Procedure

Before calibrating the electronic section of the Infant Flow™ Driver the power supply voltages should be checked. The reference and excitation voltages should be checked next and only then should the manometer and Oxygen monitor sections be calibrated.

The equipment required for this is a good quality, calibrated DVM capable of resolving 10 mV for checking the power supply rails, reference and excitation voltages and a 0 to 150 cms H_2O water column or similar accurate low pressure measuring device for calibrating the manometer and pressure relief valve. We do not recommend the use of mechanical pressure gauges for this purpose as they are inherently inaccurate. A hand pump bulb similar to those used on Blood Pressure Sphygmomanometers is also required. To check and calibrate the Oxygen monitor a supply of 4 bar pressure Medical Air and Oxygen are required.

To gain access to the electronics it is necessary to remove the top cover from the Infant Flow™ Driver. This is achieved by removing the top two M3 raised countersunk crews on each side of the cover and then sliding the cover upwards and off. The adjustment trimmers are accessible at the top left of the electronics module. They may be adjusted from the side by using a standard trim tool.

To remove the manometer section completely it is advisable to remove the four M3 raised countersunk screws on the left hand side of the device and the four M3 x 8mm pan head screws on the back panel. This will enable the complete assembly to be slid forward so that the connectors can be removed from the bottom of the processor board to allow the assembly to be come out of the housing.

CAUTION

Disconnect the unit from the mains supply by unplugging the mains cable from the mains input module on the rear panel before attempting to remove the electronics module.

Power supply checks

To check the power rails it is advisable to first disconnect the power connector CON2 from the processor board. Ensure that the mains supply is connected to the mains input module and that the voltage selector is set to the correct value. Switch on the power to the unit. The voltage rails to be checked are:

The + 5 VDC supply on pin 1 of CON2 with respect to 0 V (Digital ground) on pin 2.

The +15 VDC supply on pin 3 of CON2 with respect to 0 V (Analogue ground) on pin 4.

The -15 VDC supply on pin 5 of CON2 with respect to 0V (Analogue ground) on pin 4.

If these are all present, within 5% of their nominal value and stable the power connector CON2 may be reconnected to the processor board and the next set of tests carried out.

Display brightness set up

First the display brightness must be set. This is done by adjusting VR2 until the required brightness is obtained for the seven segment displays and then adjusting VR1 until the bar graph LEDs are of similar brightness. The light dependant resistor, LDR1, may be partially occluded to ensure that auto dimming is satisfactory.

Reference voltage checks

The reference voltage may now be checked. Connect the negative input of the DVM to the ground test point, TP3, and the positive input to TP10. A reading of 200 mV ± 10 mV should be indicated. The excitation voltage to the pressure transducer is checked on IC8 pin 6 with reference to ground, this should be 12 V ± 0.6 V.

Manometer calibration

With no equipment connected to the pressure input set the manometer to zero with VR7. Connect the water column with the hand pump bulb into a "T" piece and into the manometer pressure input on the front panel. Inflate to 10 cms H_2O and observe that there are no leaks. Check that the manometer reads 10 cms H_2O, if not, adjust VR3 to give the correct reading. Release the pressure and check that the zero reading has not changed. If it has, repeat the procedure until the readings are correct at both pressures. Pump the system up to 5 cms H_2O and ensure that the displayed value is 5 cms H_2O.

Once calibration is satisfactory pressurise the system to above 12 cms H_2O and ensure that all segments of the manometer bar graph illuminate, the high pressure LED is on, that the audible alarm sounds and the over-pressure relief solenoid is activated. Press the "MUTE" button and ensure that the audible alarm is silenced. Release the pressure in the system and press the "MUTE" button, the audible and visual alarms should cancel and the over pressure solenoid should de-activate.

Oxygen analyser calibration

There are two stages to the calibration of the Oxygen analyser, first the calibration of the galvanic fuel cell itself and secondly the calibration of the mixer monitor which enables automatic alarm setting on the set value.

To calibrate the integral Oxygen analyser the electronic module must be installed in the lower case with the leads connected to the mixer section of the driver. The Infant Flow™ driver must

also be connected to a source of Medical Air and Oxygen at 4 bar pressure. We recommend that a reference Oxygen analyser with an accuracy of ± 1% is fitted in the outlet of the driver to verify the performance.

Set the flow to 8 lpm and turn the mixer control to 100% oxygen, ensure that the reference analyser is reading 100% oxygen. Adjust VR4 until 100% is displayed in the oxygen display window. Set the mixer control to 21% oxygen and ensure that the reference analyser reads 21% oxygen. Adjust VR8 until the oxygen display reads 21%. Repeat the process until no further adjustments are necessary.

To calibrate the mixer monitor board ensure that the three way connector from the mixer control is connected to the processor board. Turn off the electronic module then press and hold the mute button whilst turning the power on again. The oxygen display will now show the setting of the mixer control. Set the mixer to 30% and adjust VR6 to give a display of 30%. Set the mixer control to 100% and adjust VR5 until 100% is shown. Repeat the process until no further adjustment is required. Check that at 60% the display reads 60 ± 2 digits. The Driver will return to normal operation after a period of 2 minutes has elapsed.

Once all of these procedures have been completed the Infant Flow™ Driver may be re-assembled.

Section 10

Mechanical Description

The mechanical components of the Infant Flow™ Driver can be separated into three items:

The enclosure

The Air/Oxygen Mixer

The Flowmeter/Pressure relief valve assembly

The enclosure is manufactured from 2mm sheet Aluminium and is protected by a powder coat epoxy based paint which is very resilient to knocks and substances that may come into contact with it.

The Manometer section is held in the case by means of four M3 raised countersunk screws on the left hand side of the enclosure and four M3 x 8mm pan head screws with shakeproof washers on the back panel. The Mixer assembly is located by the two UNC screws that hold the pole mount bracket in place. The rear panel is locked in by the gas inlet mounting plate on the rear of the Mixer.

The flowmeter mounting block fitted to the left hand side of the mixer routes all output gas from the mixer to the Oxygen analyser and either the patient circuit or to atmosphere through the over pressure relief valve system. It is mounted on the mixer by two 8-32 UNC screws and the seal is made with an O-ring between two flat machined faces. This entire assembly may be removed for cleaning or repair by removal of these two screws.

The flowmeter is removed by loosening the M4 grub screw located on the left side of the assembly. Once loosened the flowmeter can be pulled forward and the tubing on the rear detached by pushing the blue ring in towards the flowmeter whilst pulling on the tubing. If removed, it is advisable to replace the O-rings prior to re-assembly.

The flowmeter should be cleaned if contaminated and the calibration should be checked periodically (annually if the supply gases are clean and dry). To clean the flowmeter, remove it from the block and disconnect the tubing by pushing the blue ring in towards the flowmeter whilst pulling on the tubing. Remove the nut on the top which allows the ball to be removed. Clean the tube with warm soapy water only, do not use spirit based cleaners as this will damage the acrylic.

Flowmeter Calibration Check

To check the flowmeter calibration attach the Infant Flow™ driver to the medical air and Oxygen supplies and set an FIO_2 of .5 on the mixer control knob. Connect the outlet of the Infant Flow™ Driver to a test flowmeter or flow test device with an appropriate hose. Select

an indicated flow of 5 lpm on the Infant Flow™ driver flowmeter and verify that the correct flow is indicated on the test device within ± 10%. Repeat at 8, 10, 12 and 15 lpm.

Safety Pressure Relief Valve Setting

For the Infant Flow™ Nasal CPAP generator to function correctly it is necessary to have a back pressure of at least 10 times the required CPAP pressure in the delivery circuit prior to the generator. For safety reasons the Infant Flow™ driver is equipped with two pressure relief systems The first is a mechanical safety pressure relief valve designed to protect the equipment and delivery circuit. This is mounted on the flowmeter mounting block and is not accessible to the users. It is factory preset at 150 cms H_2O but should be checked periodically.

To test the setting and efficacy of the safety pressure relief valve connect the calibrated water column or similar pressure measuring system into the patient circuit. Set a flow of 8 lpm on the flowmeter and occlude the delivery tube. The pressure in the patient circuit should reach 150 cms H_2O ± 20 cms H_2O. If necessary, adjust the safety pressure relief valve to give a reading of 150 cms H_2O on the water column.

The second safety relief valve is to protect the patient and consists of an electronic solenoid valve which operates when the measured pressure in the patient circuit exceeds 11 cms H_2O. This device is mounted on a bracket on top of the Air/Oxygen mixer. Gas from the mixer is passed through a fixed regulator and the solenoid valve and acts on a silicone diaphragm located under a plate at the rear of the flowmeter mounting block. When an over pressure is detected the solenoid is activated and the pressure removed from the diaphragm. This allows the gas in the patient circuit to vent to ambient through the rear of the block and reduces the pressure in the patient circuit to virtually zero instantaneously.

It is necessary to check the pressure setting of the electronic safety system periodically. This is achieved by disconnecting the tube from the pressure regulator to the solenoid valve and connecting to an accurate pressure measuring device such as a mercury column. The regulator should be set for between 160 & 180 mm Hg. Once tested and set replace the tube on the solenoid and check the function of the electronic over pressure vent valve.

Oxygen Sensor

The sensor for the Oxygen monitor is a Teledyne R22 electro-chemical galvanic fuel cell. It is mounted on top of the flowmeter mounting block directly behind the flowmeter. It is supplied with mixed gas from the mixer through a device which limits the pressure variations which could otherwise affect it's accuracy. The sensor is expected to have an average life in excess of one year. The end of life indication for this sensor is when it is no longer possible to calibrate it accurately, however, it is recommended that it is replaced annually. Re-order part number MR22.

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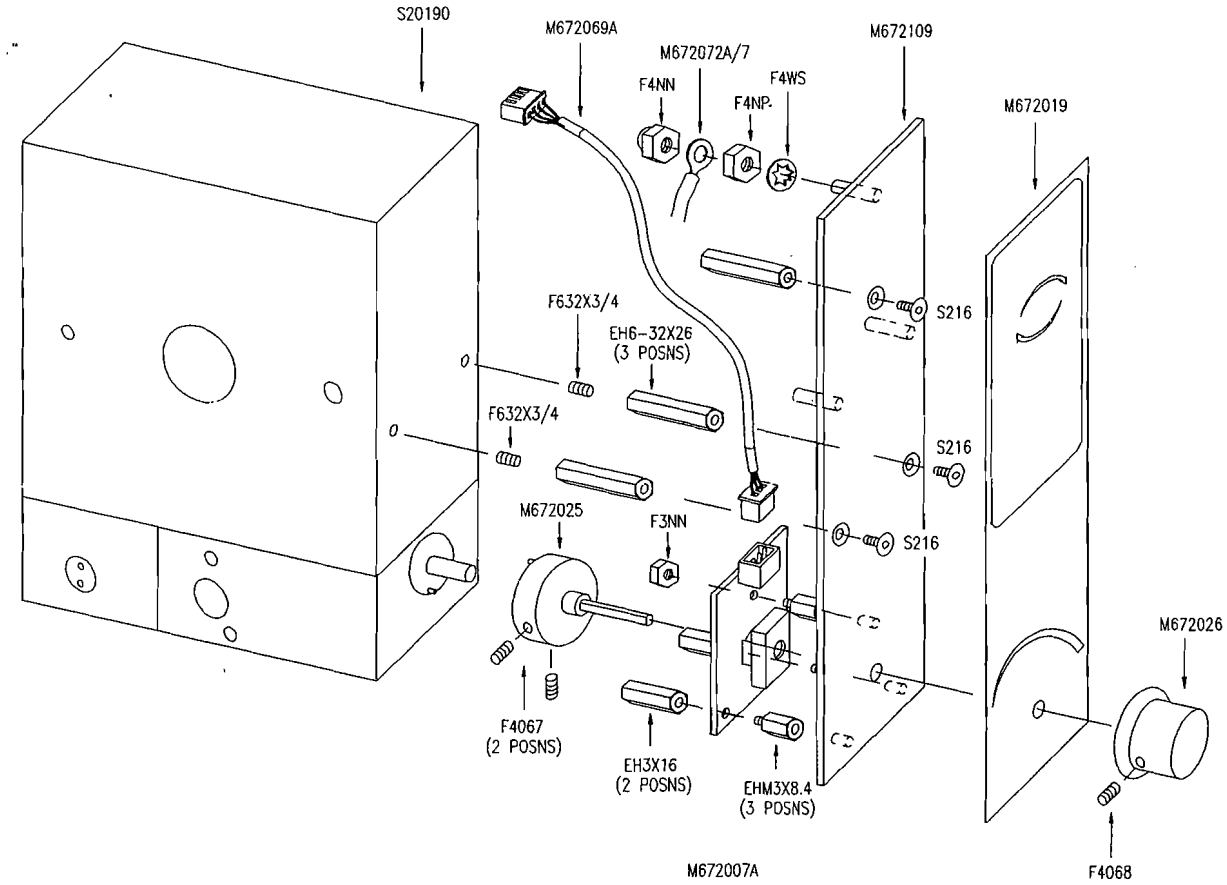

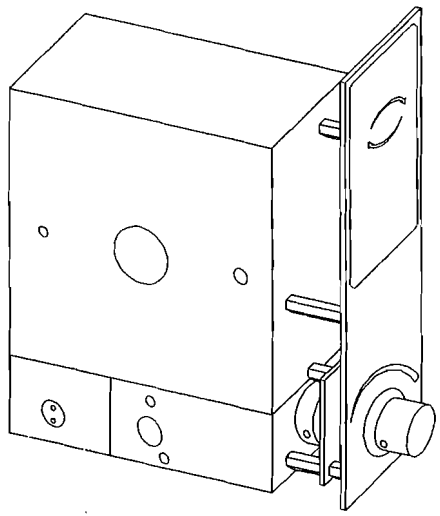

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INFANT FLOW DRIVER Mk2B

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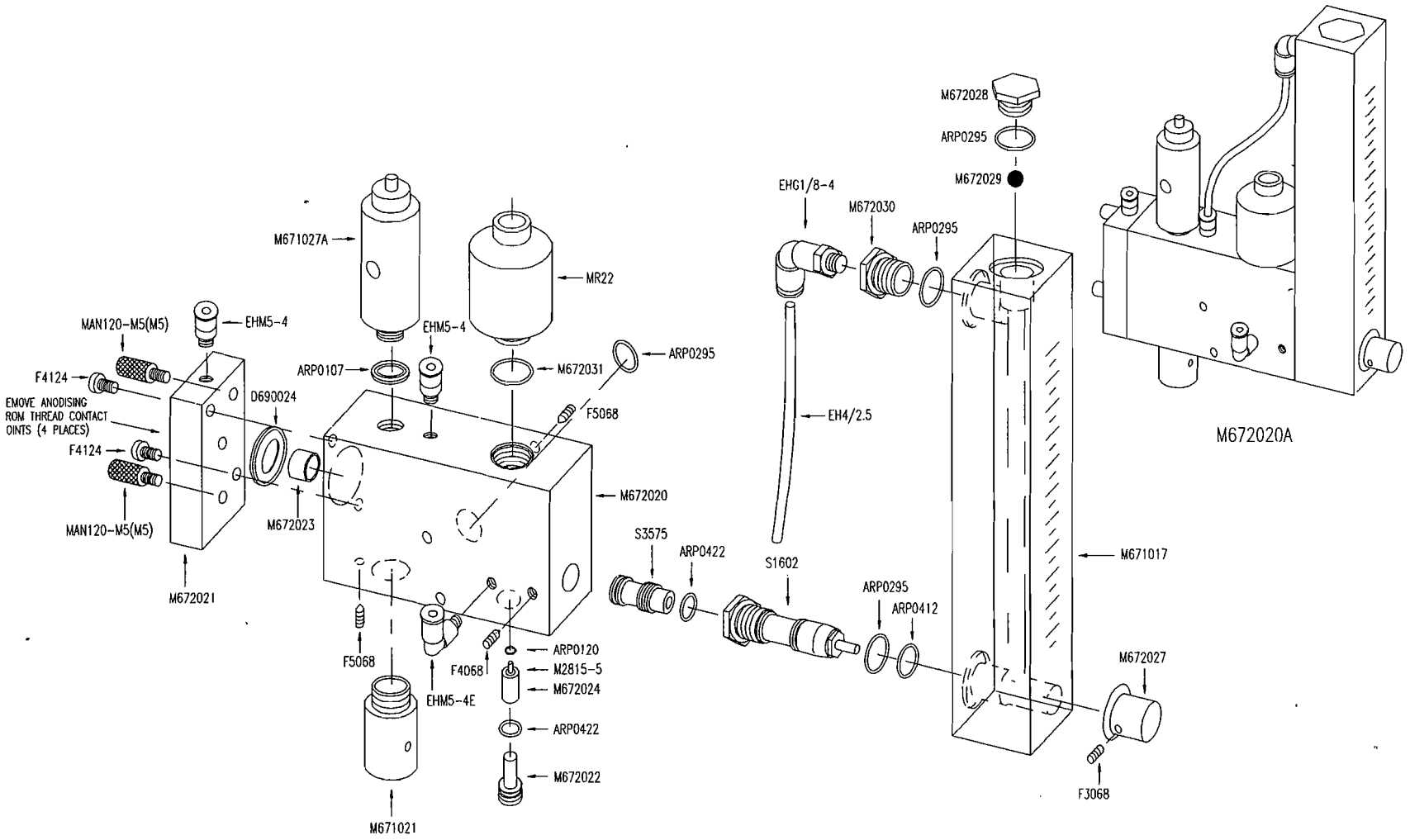

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TITLE
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INFANT FLOW DRIVER Mk2 & MK2B

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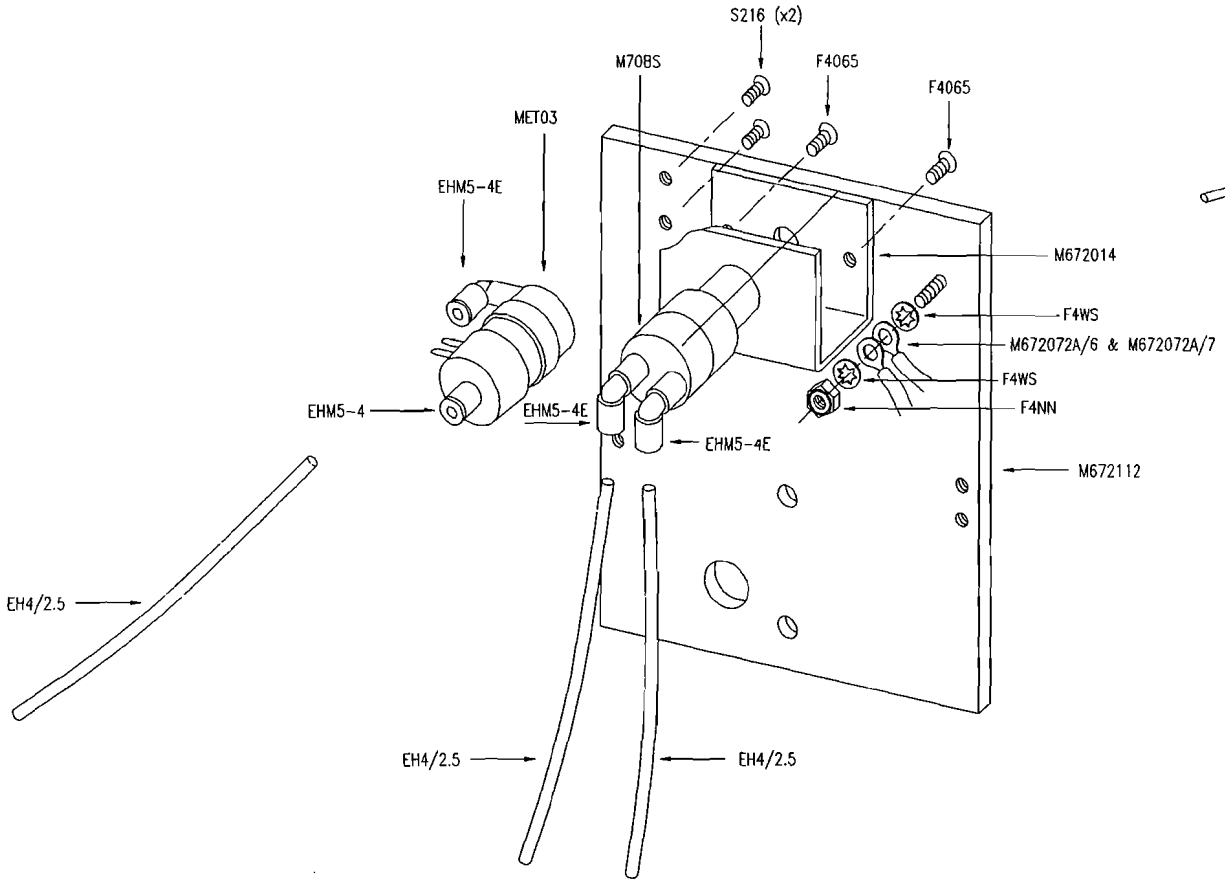

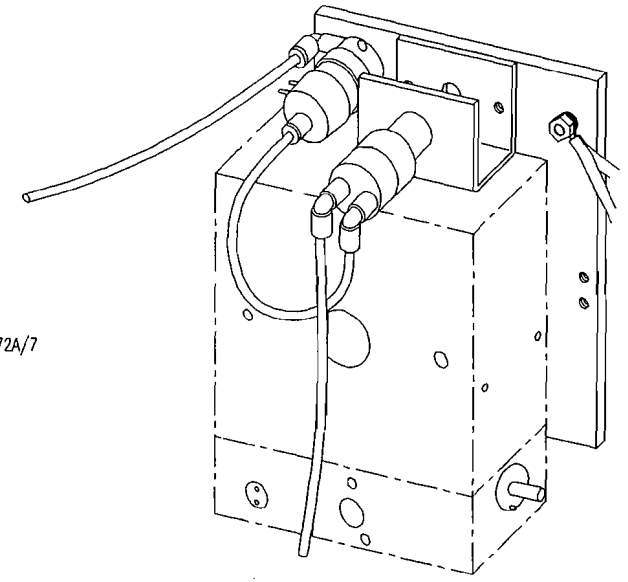

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INFANT FLOW DRIVER Mk2B

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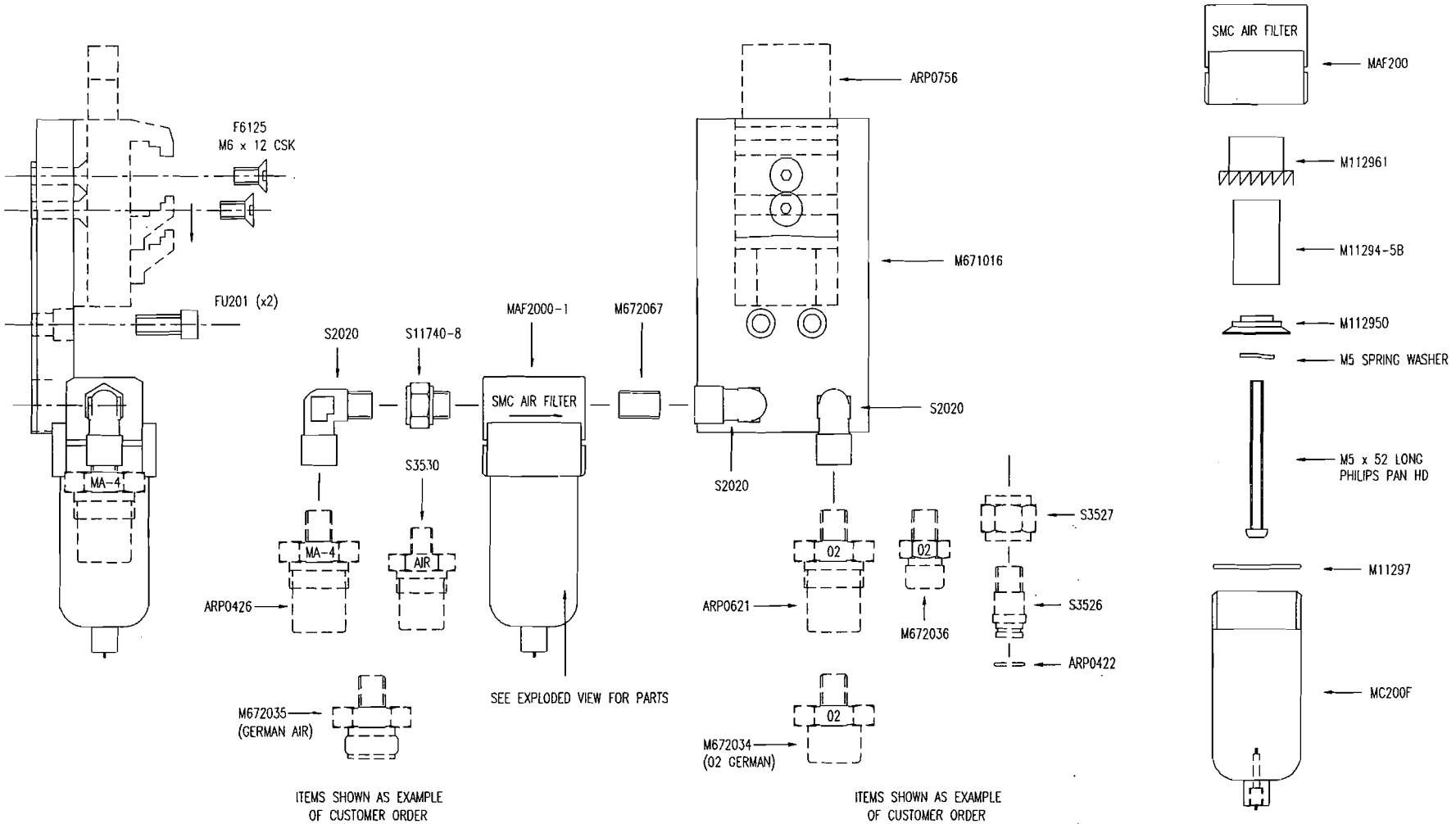

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TITLE: 02/AIR MOUNTING BLOCK ASSEMBLY FOR IFD

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Section 11

Air/Oxygen Mixer

The main body of the Air/Oxygen Mixer is a derivative of the Sechrist model 3500. This mixer has been designed for both durability and serviceability. If the criteria for the gas supplies are met and the supplies are satisfactorily clean and dry, the mixer will provide years of reliable use with relatively little care and service.

This section of the Infant Flow™ Driver service manual is dedicated entirely to the mixer and is designed to take the technician through a step by step process to:

- Test for proper operation
- Troubleshoot malfunctions
- Calibrate the mixer if necessary
- Disassemble and reassemble the mixer
- Keep the mixer working at its optimum efficiency of design

This section of the manual is split into four parts:

A Describes all tools and test equipment required to calibrate and service the air/Oxygen mixer.

B Details the testing procedures necessary to determine optimum working conditions of the Air/Oxygen mixer. If service is necessary, based on the outcome of the testing, a troubleshooting guide is given in part B to determine which component module of the mixer is involved and what procedures are recommended.

C Details the calibration procedures and those necessary for service.

D Details the dis-assembly and re-assembly procedures.

Description of the Air/Oxygen mixer

- The Air/Oxygen mixer is made up of three separate but integrated modules:
- The proportioning module does the actual gas mixing and proportions the outflow.
- The pressure balancing module takes the incoming gas pressures, with a potential differential of 2 Bar (30 PSI) and reduces this differential to 3 cms H_2O thereby nullifying the differences and equalising the incoming pressures.
- The Alarm module sounds a continuous reed alarm if the incoming gas pressures differ by more than 2 Bar (30 PSI). When the alarm is activated the gas with the highest pressure will be delivered by the mixer until supply gas pressures are restored.

Understanding the Air/Oxygen Mixer

The Infant Flow™ Driver Air/Oxygen Mixer is a device to proportion Medical Air and Oxygen at operator selected ratios for delivery to patients via the Infant Flow™ NCPAP generator.

To accomplish this task properly, several factors must be considered. First, the device must permit the operator to select a ratio of the flow of one gas vs the other gas. This is typically done by using two variable restrictors, such as needle valves, which are linked together in such a way that the effective flow areas of the two variable restrictors are inversely proportional. These variable restrictors are positioned with a calibrated control knob. Movement of the control knob will increase the effective area for the flow of one gas while decreasing the effective area for the flow of the other gas. The ratio of the areas will determine the ratio of the two gas flows. If the two gases are air and oxygen, the percentage of oxygen in the mixed gas is determined by the formula:

$$FIO_2 = \frac{(1.0 \times Q_{Oxygen}) + (.21 \times Q_{Air})}{Q_{Oxygen} \quad Q_{Air}}$$

Where Q_{Oxygen} is the flow of oxygen and Q_{Air} is the flow of air in identical units.

Dimensioning for the effective areas is determined by the desired flow range of the device. A cross section schematic view of the proportioning valve module of the Infant Flow™ Driver Mixer is shown overleaf. The calibrated control knob is attached to a threaded positioning shaft. Positioned within two sharp edged orifice seats is a double ended tapered needle valve. A spring loaded positioning device acts upon the end of the double ended valve keeping it in contact with the threaded positioning shaft.

Rotation of the control knob will move the location of the threaded positioning shaft thereby adjusting the location of the double ended needle valve relative to the two orifice seats and defining the effective flow areas for both gases.

This simple system would be all that is necessary to proportion the flow of to gases. However, if it is desired to calibrate the control knob and to maintain the ratio of the two gas flows at a constant value, the pressure differential across both orifice areas must be identical. One can easily imagine what could happen to the gas flow ratio if the Oxygen pressure increased from 4 bar, when the ratio was selected, to 7 bar. Some type of system must be used to regulate the gas pressure entering the proportioning device preferably making both gas pressures equal. If the individual gas pressures entering the proportioning device are equal and the gases flow to a common outlet for mixing, the pressure differential across each of the orifice areas will be equal. If these conditions are maintained, the ratio of the two gas flows will remain constant.

Various methods are used by different manufacturers to equalise the two gas supply pressures. Precision regulators set to equal outlet pressures, dual regulators configured such that one gas pressure is slaved to the other and devices termed nulling regulators. Nulling regulators were conceived in the 1930s for welding and liquid mixing purposes. In principle, nulling regulators use one gas pressure to control the other, but either gas may be the controlling gas. A nulling regulator will reduce whichever gas pressure is higher to a value equal to the lower gas pressure.

The Infant Flow™ Driver Air/Oxygen Mixer uses a nulling regulator to balance the two supply gas pressures before they enter the proportioning valve. This is shown schematically overleaf. Two identical needle valve/seat arrangements are configured on opposite sides of a central diaphragm. They are located so that both valve seats cannot be closed at the same time and they are designed so that the effective flow area for each gas is inversely proportional to the other. When one gas source is turned on, that gas pressure will act on the diaphragm pushing it away from the needle valve/seat until the valve closes and permits no flow of the gas. If the other gas source is turned on, it will find its needle valve/seat open and the gas pressure passing through this open seat will act upon the diaphragm. The diaphragm will then move to a position where the pressure acting upon each side of the diaphragm will move away from the higher pressure. When the diaphragm moves in this way, the needle/seat which is the source of the higher gas pressure will close down, reducing pressure on the diaphragm. At the same time, the opposite needle valve/seat is opened. Thus, the system will null out differences in the gas pressures until they are equal. These equal gas pressures are then presented to the proportioning valve for mixing at the desired ratio.

As stated previously, a characteristic of a nulling regulator is to create an outlet gas pressure equal to the lower of the two inlet gas pressures. In this case, if one of the inlet pressures is zero, the outlet pressure will be zero. It is desirable to keep pneumatic respiratory care equipment operating even with the inadvertent loss of one of the supply gases. Therefore a device is required which will bypass the nulling regulator with the remaining supply gas and simultaneously activate an alarm to alert attending personnel. Such a bypass/alarm system is incorporated in the Infant Flow™ Driver Air/Oxygen Mixer.

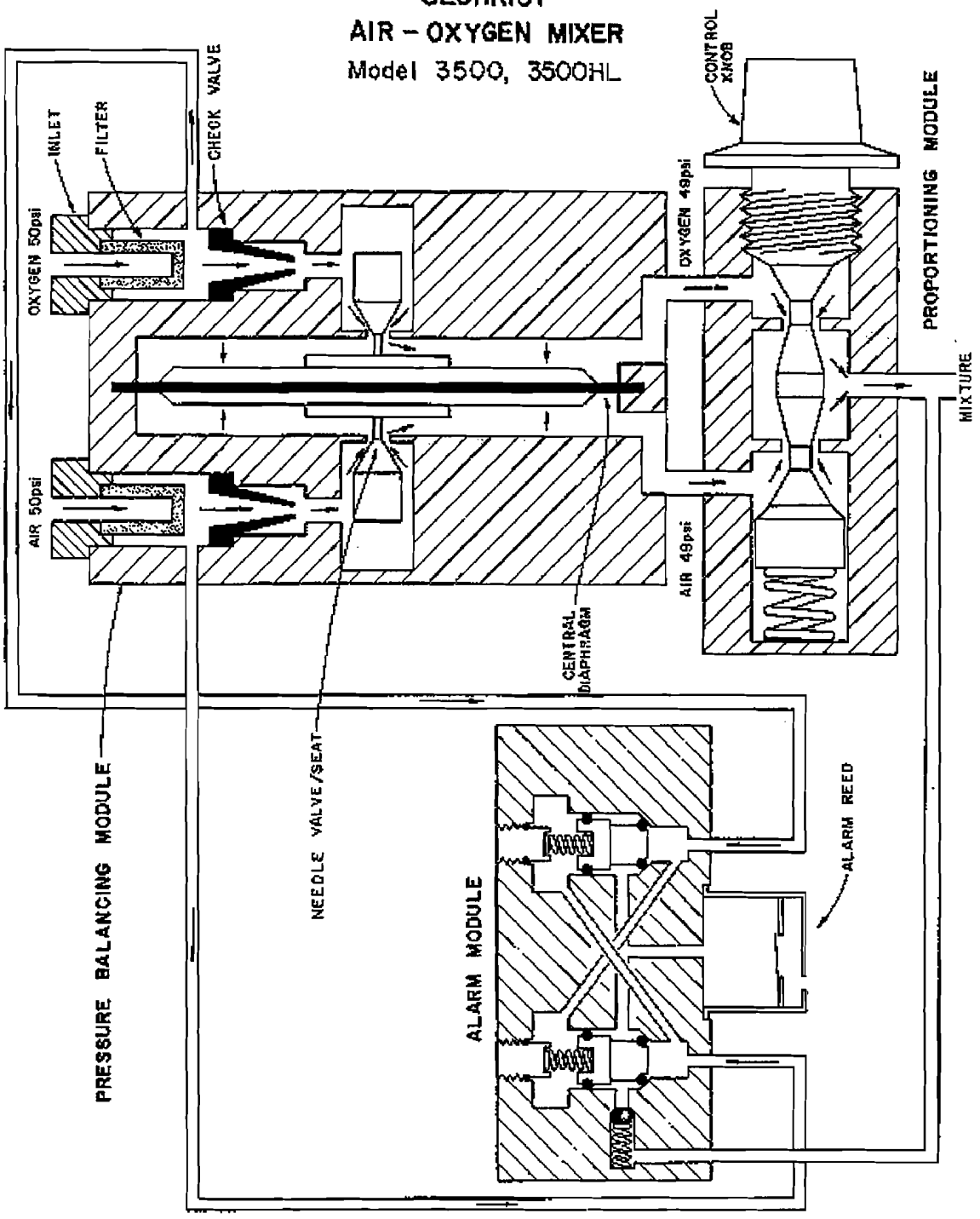

FIGURE 2

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Schematic representation of the Air/Oxygen Mixer

This device is depicted schematically on the previous page. The supply pressure of air and oxygen are delivered to this module via internally drilled channels. Cross drilling within the module presents the air and oxygen pressures on opposing ends of two identical moveable pistons. These pistons are fitted with sealing O-rings and are nominally seated with the force of a compression spring.

The sealing O-rings are of different diameter on the ends of the piston. Therefore the forces generated by the inlet gas pressures are close to the same value. If, however, one of the gas pressures should drop in relation to the other, the resulting forces will cause the piston to move back from its seated position and in so doing open a flow channel from the higher of the two inlet pressures to the Proportioning Module outlet. When this occurs, the alarm reed will be activated and the higher gas pressure will enter the outlet manifold of the proportioning valve to supply gas pressure to the outlet port, bypassing its normal route.

Restoring the lower gas pressure will re-seat the moved piston. A one way check valve is located in the bypass/alarm to prevent the normal gas mixture from activating the alarm reed. The pressure difference in the inlet gas pressures required to activate the alarm is determined by the dimensioning of the piston seal areas and the seating spring force.

Filters are incorporated in both of the gas inlet connections. One way check valves are also located in both of the gas inlet connections to prevent the cross flow of one gas supply to the other source.

Special tools and accessories are required to calibrate, disassemble and reassemble the Infant Flow Driver Air/Oxygen Mixer. No service work on the mixer should be undertaken unless these special tools are available.

SPECIAL CALIBRATION AND ASSEMBLY TOOLS

Air/Oxygen Mixer Tool Kit		Part No S3651
AT1:	1/8" spanner wrench	Part No S3654
AT2:	3/8" spanner wrench	Part No S3653
AT3:	5/8" spanner wrench	Part No S3652
AT4:	Bypass plate	Part No S3655
	Brass Plug 10-32	Part No S3635
	Brass 10-32 x 1/16" fitting	Part No S310
	Roll Pins (8)	Part No S3537
	Screws (2) 6-32	Part No S3559
	O-rings - 008	Part No S3534

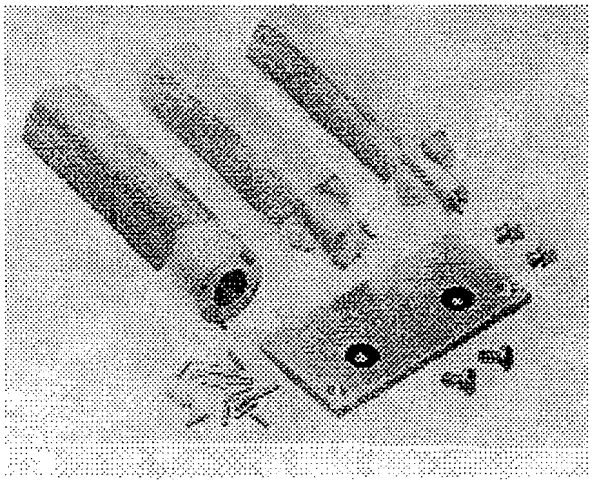

Figure 1 - Special Assembly Tools

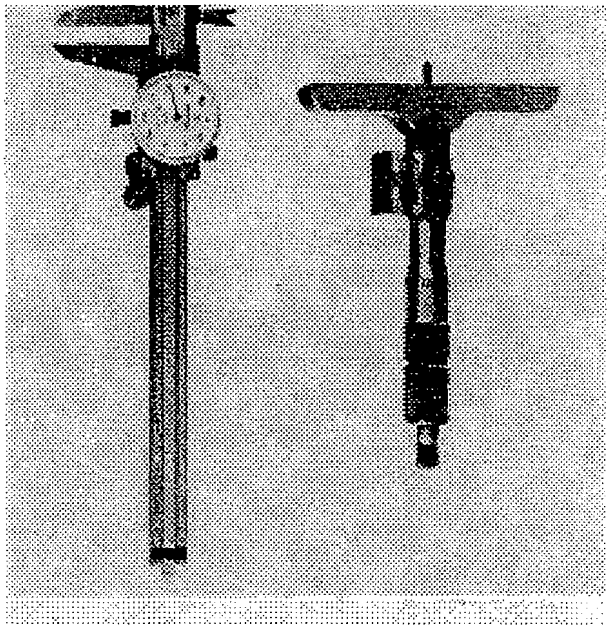

Figure 2 - Calliper & Micrometer

GENERAL CALIBRATION AND ASSEMBLY TOOLS

1/16"	Allen Wrench	7/16" Open End Wrench
5/64"	Allen Wrench	1/2" Open End Wrench
7/64"	Allen Wrench	3/4" Open End Wrench
9/64"	Allen Wrench	1/4" Nut Driver
3/16"	Allen Wrench	Internal Tru-arc Circlip Pliers
1/4"	Allen Wrench	Needle Nose Pliers
3/32"	Allen Wrench	Soft Mallet
	Medium Blade Screwdriver	
	Precision Calliper	(see figure 2)
	Precision Depth Micrometer	(see figure 2)
	Lubricant for O-rings	Krytox 240 AC (Dupont)

EQUIPMENT REQUIRED FOR TEST SYSTEM

Oxygen High Pressure Hose with Appropriate Fittings
Air High Pressure Hose with Appropriate Fittings
Oxygen Regulator, Adjustable with Pressure Gauge 0-4 Bar (60 PSI)
Air Regulator, Adjustable with Pressure Gauge 0-4 Bar (60 PSI)
Oxygen Analyser (Calibrated to + - 1% Accuracy, Readout Accurate to 1% Increments)
Sampling Reservoir (Bottle or Tube)
Oxygen Analyser (Calibrated to + - 1% Accuracy, Readout Accurate to 1% Increments)
Sampling Reservoir (Bottle or Tube)
Pressure Gauge 0-4 Bar (60 PSI)

ROUTINE MAINTENANCE REQUIREMENT

Before attempting to calibrate or repair the Air/Oxygen Mixer, a qualified hospital technician should be familiar with the design and function of the device. The following instructions utilise a numbering system which is to be followed in sequence. All parts are numbered and can be reviewed on the exploded parts diagrams contained herein.

Air/Oxygen Mixer Overhaul Kit (Part No S3658)

To ease the task of servicing the Air/Oxygen mixer the overhaul kit includes all of the items required to carry out a full service under one part number. The kit includes the following:

MIXER OVERHAUL KIT S3658		
Part Number	Description	Quantity
Items for the Proportioning Module		
S3548	Nitrile O-Ring, BS 006	1
S3513	Nitrile O-Ring, BS 011	5
S3521	Nitrile O-Ring, BS 012	2
S3534	Nitrile O-Ring, BS 008	4
S3520	Nitrile O-Ring, BS 014	1
S3535	Packing Washer, Nylon	1
S3533	Adjustment Shaft	1
Items for the Pressure Balancing Module		
S3521	Nitrile O-Ring, BS 012	4
S3517	Nitrile O-Ring, BS 007	2
S3566	Nitrile O-Ring, BS 018	2
S3626	Nitrile O-Ring, BS 112	2
S3520	Nitrile O-Ring, BS 014	2
S3515	Spring, SS, LC-014B-4SS	2
S3510	Diaphragm Assembly	1
S3525	Duck Bill Check Valve	2
Items for the Alarm/Bypass Module		
S3639	Silicone O-Ring, BS 008, 70 DUR	3
S3548	Nitrile O-Ring, BS 006	2
S3618	Silicone O-Ring, BS 010, 50 DUR	2
S3569	Nitrile O-Ring, BS 025	1
S3520	Nitrile O-Ring, BS 014	4
S3619	Spring, 302 SS	2
S3637	Spring, Custom	1
S3636	Check ball, 7/32" Diameter	1
Items for the Filtration System		
S3529E	Water Trap filter	1
S3522K	Air and Oxygen Inlet Filter Kits	2
Items for Flowmeter Block		
S3578	Nitrile O-Ring, BS 013	1

B TEST PROCEDURE

In order to determine the optimal function of the Air/Oxygen Mixer and the potential need for calibration, service or repair, complete the following test procedures.

B.1.0 **Initial Test System Set Up**

B.1.1 Connect the Mixer to clean and dry Medical Breathing Oxygen and Medical Breathing Air supplies which are independently adjustable from 0 to 4 Bar (0 to 60 PSI).

B.1.2 Connect a flowmeter to the outlet of the Mixer.

B.1.3 Direct the flow from the flowmeter to a sampling reservoir (ie bottle or tube), making sure that no room air is being entrained to dilute the mixture.

B.1.4 Insert the Oxygen analyser probe into the sampling reservoir.

NOTE: The Oxygen analyser must be calibrated and accurate to ± 1%.

B.1.5 Set a flowrate of 7 lpm

B.2.0 **Proportioning Module**

B.2.1 Set the Oxygen and air pressure to 4 Bar (60 PSI)

B.2.2 Compare the Oxygen analyser readings to the Mixer settings of .21, .40, .80 and 1.0.

B.2.3 The Mixer has a specified accuracy of ± 3%. If the FIO_2 varies more than ± 4% between the Mixer and Oxygen analyser reading, calibration or service may be necessary (see Troubleshooting Guide).

B.2.4 There is a constant bleed of mixed gas from the bottom of the Proportioning Module. This bleed is approximately 3.5 lpm and is needed to maintain accurate FIO_2s at very low flows. These bleed rates are predetermined by the factory and cannot be reset in the field.

B.3.0 **Pressure Balancing Module**

B.3.1 With same test system set up as above, select an FIO_2 of .60 and observe the Oxygen analyser reading.

B.3.2 Vary the inlet pressures to the Mixer to 2.6 Bar (40 PSI) 0xygen and 4 Bar (60 PSI) air and then to 4 Bar (60 PSI) Oxygen and 2.6 Bar (40 PSI) air. If the FIO_2 varies by more than ± 1% from the initial Oxygen analyser reading, calibration or service may be necessary (see Troubleshooting Guide).

B.4.0 **Alarm Module**

B.4.1 Set air and Oxygen supplies to 4 Bar (60 PSI), the alarm should be silent.

B.4.2 Slowly reduce the air inlet supply, the alarm should sound at between 1.6 and 1.9 Bar (24 and 28 PSI) and the Oxygen analyser should read 100%. Increase the air inlet supply pressure slowly to 4 Bar (60 PSI), the alarm should reset at or before 2.7 Bar (40 PSI).

B.4.3 Repeat step 4.2 varying the Oxygen inlet supply pressure, when the alarm sounds the Oxygen analyser reading should read 21%.

B.4.4 If the alarm does not function as per the above specifications, calibration or service may be necessary (see Troubleshooting Guide).

B.5.0 **Air Inlet Filtration System (most frequent service required)**

B.5.1 To test the pressure drop through the water/trap filter or the internal air inlet filter, a test port has been provided on the rear of the Mixer above the air inlet.

B.5.2 With a 1/4" nut driver, remove the plug from test port and install a Brass 10-32 x 1/16" fitting (Part No S310, see Tool Kit).

B.5.3 Connect a high pressure gauge (0 to 4 Bar or 0 to 60 PSI) to the 10-32 fitting.

B.5.4 With the flow set at 7 lpm set the mixer control knob to .21. Observe the pressure indicated at test port.

B.5.5 If the difference between the pressure at the test port and the inlet pressure is greater than 0.65 Bar (10 PSI) replace either or both air inlet filters (see Routine Maintenance section).

NOTE: The Mixer will maintain the delivered FIO_2 within ± 1% of the selected value with fluctuations of the supply pressures. The additional 2% error is caused by the readability of the set point and scale error.

NOTE: The outlet pressure of the Mixer will always be slightly lower than the lower of the two inlet pressures.

TROUBLE SHOOTING GUIDE

PROBLEM	POSSIBLE CAUSE	CORRECTION
FIO_2 not accurate	Oxygen analyser out of calibration (most common problem)	Re-calibrate Oxygen analyser
	Improper purity of supply gases	Check quality of supply gases
	Wrong gas supplied to inlet	Assure outlets and hoses are correct
	Front or rear seats worn	Clean and replace seats
	Calibration of proportioning valve incorrect	See Calibration for Pressure Balancing Module
	Pressure Balancing Module malfunctioning	
Knob is hard to turn	Knob has been bumped bending adjustable shaft	Replace adjustable shaft and re-calibrate

PRESSURE BALANCING MODULE		
PROBLEM	POSSIBLE CAUSE	CORRECTION
FIO_2 Change > 1% when testing	Air or Oxygen inlet filter dirty causing > 1.3 Bar (20 PSI) difference	Replace filter
	Regulator needle(s) out of calibration	Calibrate
	O-ring(s) on regulator seat damaged causing leak	Replace O-rings and re-calibrate
	Contamination from supply gases	Clean and re-calibrate

ALARM MODULE		
PROBLEM	POSSIBLE CAUSE	CORRECTION
Continuous alarm with both inlet pressures equal	Dirty inlet filter(s)	Dirty inlet filter(s)
	Bypass check ball leaking	Need to clean check ball and seat (see Disassembly of Alarm Module)
	Alarm Module adjustments out of calibration	See Calibration Section
Alarm not sounding with loss of one pressure	Defective Reed	Replace reed
	Alarm Module adjustments out of calibration	See Calibration Section
	Alarm poppets stuck	Clean, lubricate and re-calibrate

The Air/Oxygen Mixer must be calibrated and tested in conditions similar to the environment for which the Mixer was designed.

Medical breathing Oxygen and medical breathing air sources will be required to calibrate the system. A calibrated Oxygen analyser is necessary (be sure the Oxygen analyser is calibrated and that the accuracy of the readout is in 1% increments or better) and a flowmeter is used to sample the gas mixture being delivered to the Oxygen analyser.

To calibrate the Air/Oxygen Mixer, the system must be broken down into the three modules: the Proportioning Module, the Pressure Balancing Module and the Alarm Module (see Disassembly and Re-assembly Section).

NOTE

The order of calibration given must be followed ie the Pressure Balancing Module must be calibrated before the Proportioning Module can be connected and calibrated and the Pressure Balancing Module and Proportioning Module must be calibrated together before the Alarm Module can be installed and calibrated.

C.1.0 **Pressure Balancing Module** (See Figure 3)

C.1.1 To calibrate the Pressure Balancing Module, all accessory parts, pole mount, wall mount, flowmeter and Proportioning and Alarm Modules must be removed.

C.1.2 Using a 3/16" Allen wrench, remove the four screws, Part No S3507, from the air block, Part No S3505, and divide the Pressure Balancing Module into three sections. The air block, Part No S3505, the Oxygen block, Part No S3506, and the diaphragm assembly, Part No S3510.

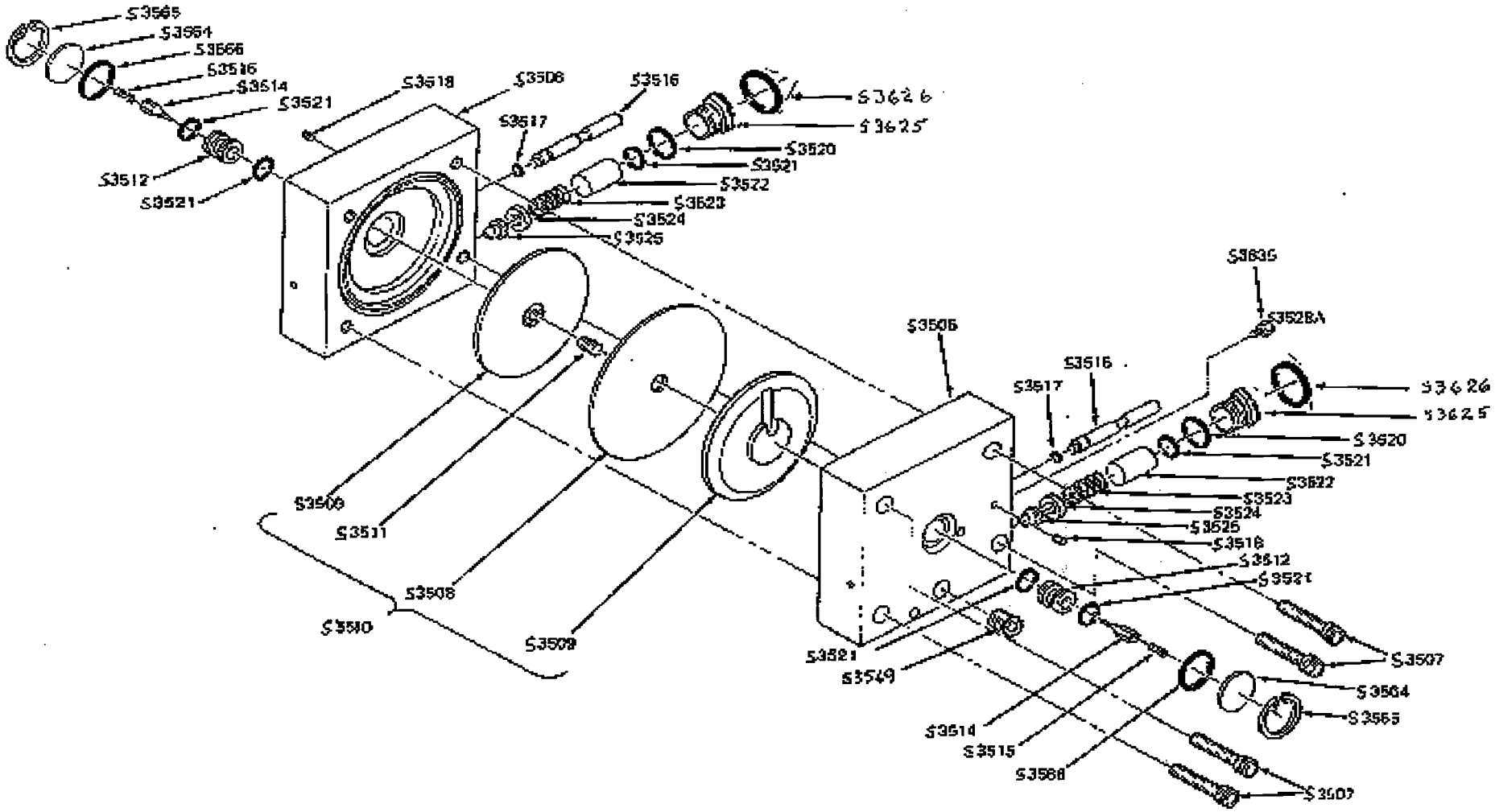

Figure 3 - Pressure Balancing Module

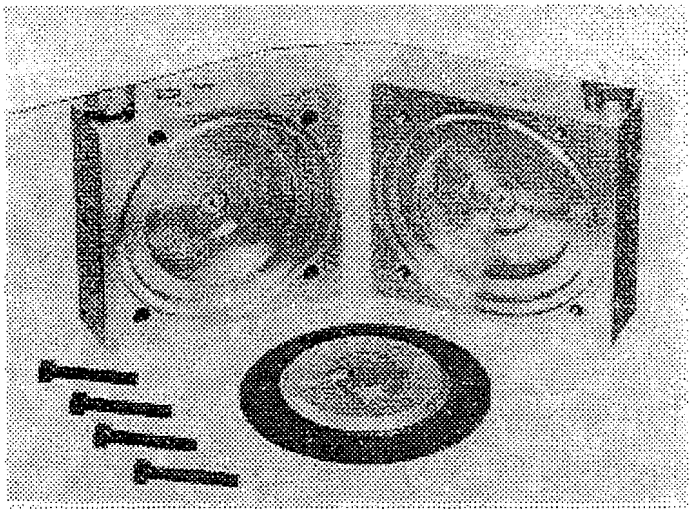

Figure 4 - Three Sections of the Pressure Balancing Module

NOTE: The Air and Oxygen blocks are identical for calibration purposes.

C.1.3 Using a precision calliper (see Tool List) measure the thickness of the diaphragm assembly (the distance between the 2 diaphragm support plates) (see figure 5). The distance should be between 0.800" and 0.810".

Regulator Needle Setting Table	
Diaphragm Thickness	Micrometer Reading
.810	.3975
.809	.3970
.808	.3965
.807	.3960
.806	.3955
.805	.3950
.804	.3945
.803	.3940
.802	.3935
.801	.3930
.800	.3925
.799	.3920
.798	.3915
.797	.3910
.796	.3905
.795	.3900
.794	.3895
.793	.3890
.792	.3885
.791	.3880
.790	.3875

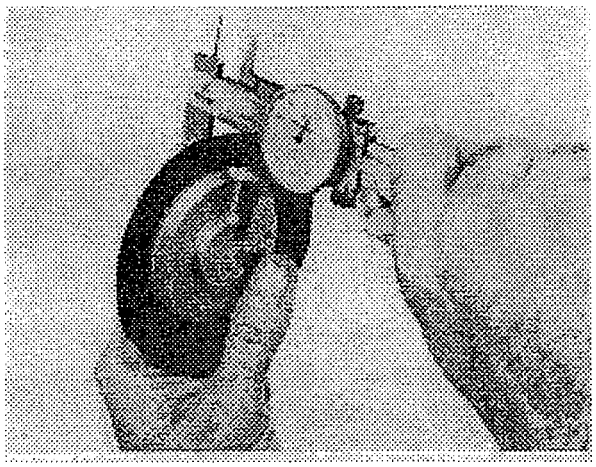

Figure 5 - Holding Calliper

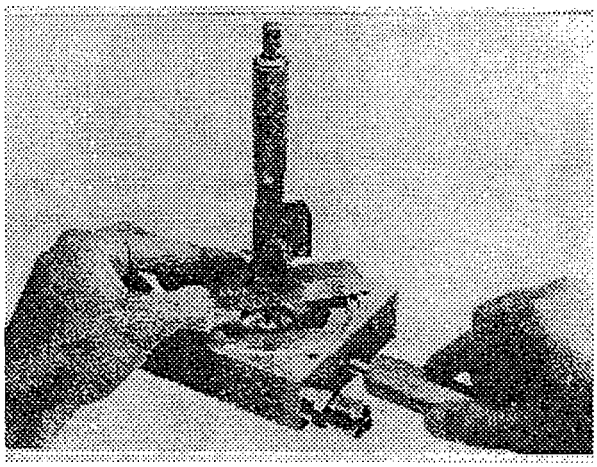

Figure 6 - Micrometer across block

C.1.4 Locate the measured diaphragm assembly thickness in the Regulator Needle Setting Table and read across to find the corresponding depth micrometer setting.

C.1.5 Set the depth micrometer (see Tool List) to the setting indicated in the table and rest the micrometer across the block cavity (see figure 6).

C.1.6 Using either a 1/16" or a 5/64" Allen wrench loosen the set screw, Part No S3518. Using the special Assembly Tool AT1 insert into the eccentric adjuster, Part No S3516, and begin turning clockwise (see figure 6).

C.1.7 The regulator seat, Part No S3512, and the regulator needle, Part No S3514, will move up and down.

NOTE: Calibration must be done on the downstroke of the regulator seat and needle.

C.1.8 As the spanner wrench is being turned (always clockwise), the needle and seat will arrive at top dead centre and start back down. As it starts back down, start sliding the depth micrometer back and forth across the needle: do not bend the needle.

C.1.9 Slowly turning the spanner wrench in very small increments, listen for the tapping noise of the depth micrometer contacting the needle as it slides over it.

C.1.10 At some point in the downstroke of the needle, the depth micrometer will no longer come in contact with the needle. As soon as the tapping noise ceases, the regulator needle is in the proper position.

C.1.11 Using either a 1/16" or a 5/64" Allen wrench, tighten up set screw, Part No S3518, to secure the calibration.

C.1.12 Calibrate both blocks in this manner and reassemble the Pressure Balancing Module by replacing the diaphragm assembly and securing the two block halves with the four screws, Part No S3507, hand tightening only.

NOTE: Position the two halves so that they are flush (make sure that the two halves of the module face, where the Proportioning Module mounts, are flush).

C.1.13 Tighten the four screws, Part No S3507 in a cross pattern to evenly distribute pressure.

C.1.14 The Pressure Balancing Module is now calibrated.

NOTE: At the end of all calibration procedures, a test of the Pressure Balancing Module must be performed to confirm the calibration.

C.2.0 Proportioning Module (see figure 7)

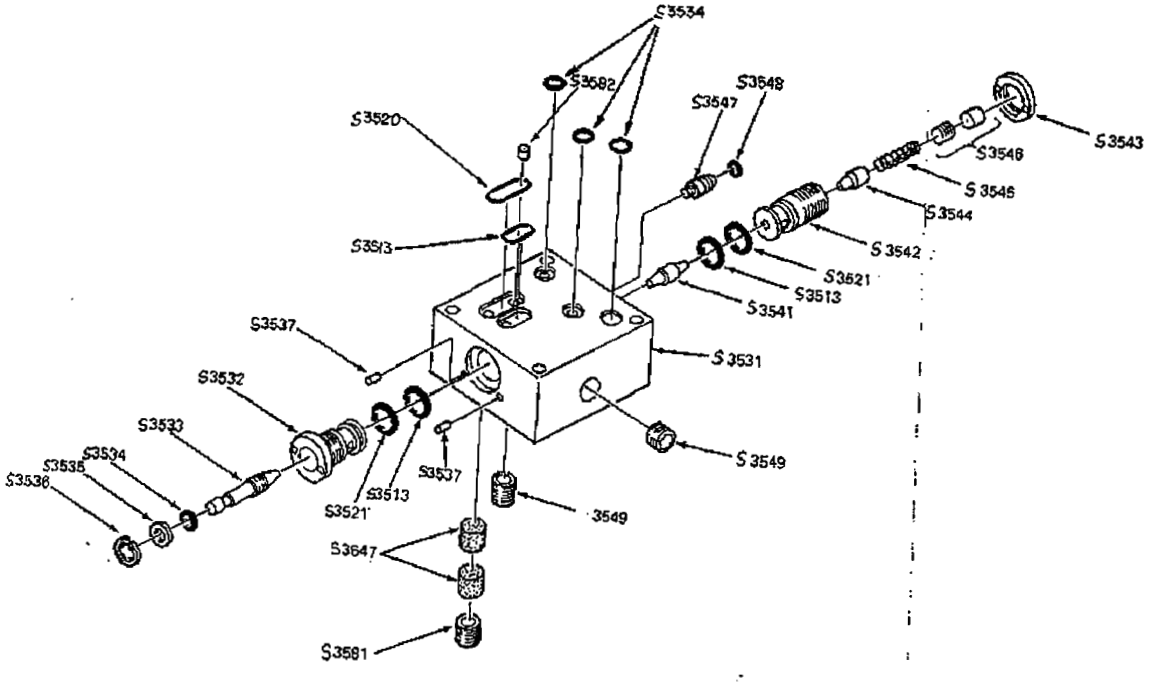

Figure 7 - Proportioning Module

C.2.1 Using a 9/64" Allen wrench, attach Proportioning Module to Pressure Balancing Module with four screws, Part No S3550.

NOTE: Be sure O-rings are in place between the Proportioning Module and Pressure Balancing Module.

C.2.2 Install the faceplate, Part No M671019, with two screws, Part No S3559, and affix a new overlay, Part No M671019, to the panel.

C.2.3 Install Assembly Tool AT4 (see Tool List) to occlude the high pressure inlet ports to the Alarm Module from the Pressure Balancing Module.

C.2.4 Using a pair of needle nose pliers remove the bypass nipple, Part No S3547, (see figure 8).

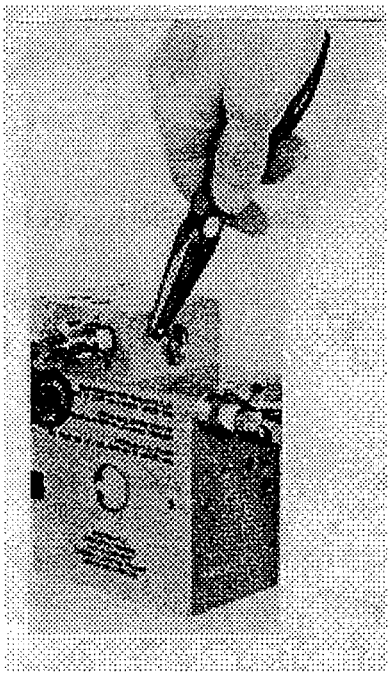

Figure 8 - Showing needle nose pliers removing nipple

CAUTION

Grasp the nipple at the base next to the Proportioning Valve Block - not on the end or the nipple may be damaged.

C.2.5 Using a 1/4" nutdriver, install the brass plug, Part No S3635, (see Tool List) into bypass nipple port.

C.2.6 Install the flowmeter mounting block.

C.2.7 Connect the Medical Breathing Air and Oxygen supplies to the respective gas inlets.

C.2.8 Connect the proportioning outlet to the calibrated Oxygen analyser.

NOTE: The Oxygen analyser must be calibrated and the accuracy of the readout scale must be within ±1%. All analyser readings specified throughout the calibration procedures are expressed as true fractional Oxygen concentrations.

C.2.9 Select a flow of 7 lpm to the Oxygen analyser.

C.2.10 Turn adjustment shaft, Part No S3533, by hand until the Oxygen analyser reads 30%.

C.2.11 Attach the Mixer control knob, Part No S3538, to the adjustment shaft, Part No S3533, and align the black indicator on knob with .30 position on the faceplate. Using a hex wrench, tighten the set screw just enough to attach knob; do not fully tighten the set screws at this time.

C.2.12 Turn the knob to .90 position and check the Oxygen analyser reading.

C.2.13 Using special tool AT3, loosen the jam nut, Part No S3543. Using special tool AT2, adjust the rear seat, Part No S3542, until the Oxygen analyser agrees with knob reading of .90 ± 1% (see figure 9).

C.2.14 Turn the knob to the .21 position (making sure that the knob hits the stop pin), then up to the .30 position on mixer, the Oxygen analyser should read 30 ± 1%. If necessary, rotate the knob until a reading of 30 ± 1% is obtained on the Oxygen analyser, and reposition the knob to align the knob indicator with the .30 position on the faceplate.

C.2.15 Turn the knob to the .90 position; adjust the rear seat until the Oxygen analyser reads 90 ± 1%.

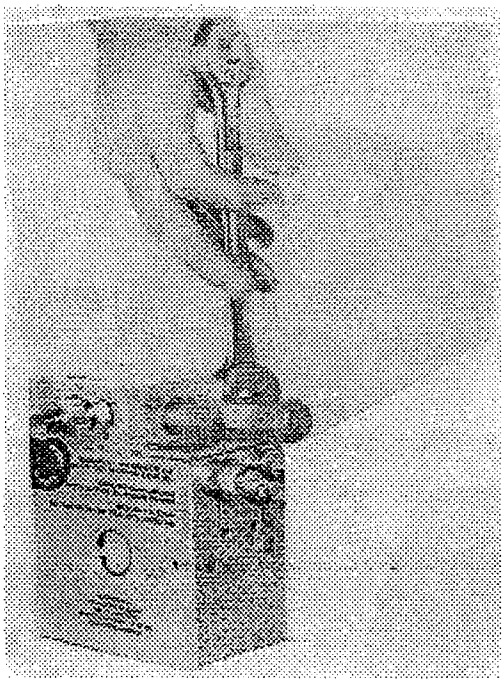

Figure 9 - Adjusting the Rear Seat on the Proportioning Module

C.2.16 Repeat steps 2.14 and 2.15 until proper readings are recorded.

C.2.17 Turn knob to 1.0 position and make sure that the Oxygen analyser reads at least 98% (and no higher than 99.5%) and that the knob is hitting the end stop pin.

CAUTION

If resistance is met before stop pin at 1.0 position is reached, do not force the knob. Re-adjust rear seat slightly - just enough to allow free range of movement to stop pin position. Recheck the calibration as described above.

C.2.18 Using special tool AT3, tighten the jam nut, Part No S3543, to secure the calibration of the rear seat.

NOTE: When tightening the jam nut the FIO_2 may drop due to movement of rear seat. This can be compensated for by setting the Mixer knob at .90 position and adjusting the rear seat until the Oxygen analyser reading is slightly above 90% (around 91%). When the jam nut is tightened the Oxygen analyser should come down to 90%.

C.2.19 Verify that the full range of positions can be obtained within a ± 3% variation.

C.2.20 When all calibrations are completed use an Allen wrench to tighten the knob set screw(s), Part No S223.

C.2.21 Turn the gas supplies "OFF", remove the bypass plate AT4 and insert the bypass nipple, Part No S3547.

C.2.22 The calibration of Proportioning Module is now complete.

C.3.0 **Alarm Module** (see figure 10)

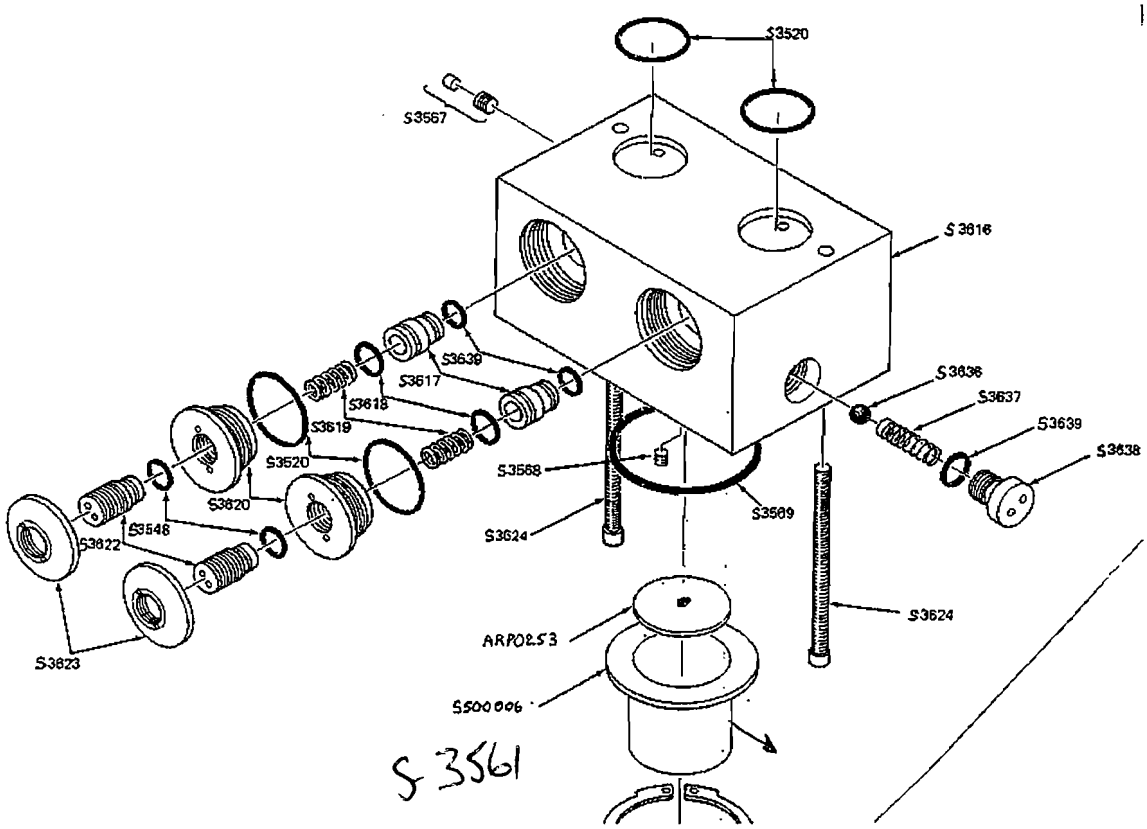

Figure 10 - Bypass/Alarm Module

C.3.1 Slide the Alarm Module onto the bypass nipple, Part No S3547, and secure the Alarm Module to the Pressure Balancing Module with two screws, Part No S3624.

NOTE: Be sure O-rings are in place between modules.

C.3.2 With the Mixer still attached to gas supply lines the calibration of Alarm Module can now be performed.

C.3.3 Test procedure for acceptable alarm bleed response: turn the Oxygen valve "ON" and regulate to 4 Bar (60 PSI) leave the air "OFF", the alarm should sound. Turn the Oxygen down to 2 Bar (30 PSI), the alarm should sound continuously down to this level. If it does sound throughout the 2 to 4 Bar range the alarm bleed is fully functioning.

CAUTION

The alarm bleed set screw, Part No S3568, is calibrated at the factory and should not require calibration.

C.3.4 If the alarm is not functioning properly, check the alarm reed, Part No S500006, before performing the alarm bleed calibration. The alarm reed may require adjustment or be damaged or contaminated. To adjust the reed, use a small instrument screwdriver through the centre hole of the black cover cap, Part No ISU010, adjust the screw to obtain the alarm sound over the range.

C.3.5 If the alarm bleed does need calibration, use tru-arc circlip pliers to remove the tru-arc ring, Part No S3570, that holds the alarm reed cap assembly in place and remove the alarm reed cap assembly complete, Part No S500006, do not attempt to disassemble the alarm reed cap assembly.

C.3.6 If alarm does not sound at lower range of 2 Bar (30 PSI) the flow to reed needs to be increased. This is achieved by adjusting the alarm bleed set screw, Part No S3568, clockwise. If alarm does not sound at the upper range of 4 Bar (60 PSI), or hesitates when the cap is occluded, flow to reed must be decreased by adjusting the alarm bleed set screw counter clockwise. After adjustment the reed cap must be placed in its seat and held by hand to verify the alarm function. When the full range of alarm has been tested and verified install the tru-arc ring over the reed cap making sure that the O-ring, Part No S3569, is in place to seal the reed cap assembly.

CAUTION

Do not occlude the alarm outlet ports as permanent damage to the alarm reed will be caused.

C.3.7 To calibrate the bypass alarm Oxygen calibration adjuster, Part No S3622, turn the Oxygen and air to "ON" and regulate to 4 Bar (60 PSI).

NOTE: The Oxygen calibration adjustment is located under the air inlet and the air calibration adjustment is located under the Oxygen inlet.

C.3.8 The alarm should be silent.

C.3.9 Using the gas supply regulators set the air supply to 4 Bar (60 PSI) and slowly reduce the Oxygen supply. The alarm should sound at between 1.6 and 2 Bar (24 and 30 PSI).

C.3.10 If no alarm sounds, loosen the jam nut, Part No S3623, and turn the Oxygen adjuster (located under the air inlet, Part No S3622) counter clockwise slowly until the alarm sounds.

C.3.11 If the alarm is sounding when the gas supply is turned on, turn the Oxygen adjuster (under the air inlet) clockwise until alarm stops then turn counter clockwise just until the alarm sounds.

C.3.12 Reduce the Oxygen pressure to zero to relieve pressure within the hose from the Mixer to regulator.

C.3.13 After venting, no pressure should build up on the Oxygen regulator gauge.

NOTE: If pressure does starts to build up on the Oxygen gauge the duck bill valve, Part No S3525, in the Oxygen inlet is leaking and causing a back flow of air into the Oxygen inlet. Clean or replace the duck bill valve as needed (see disassembly of gas inlet valves in Routine Maintenance Section.

C.3.14 Open the Oxygen pressure to 4 Bar (60 PSI), the alarm should stop sounding at or before 2.7 Bar (40 PSI).

C.3.15 Tighten the jam nut over the Oxygen calibration adjuster to secure the calibration.

C.3.16 To calibrate the bypass alarm air calibration adjuster, complete steps 3.5 through 3.7, replacing air for Oxygen in the instructions, remembering that the air adjuster is located under the Oxygen inlet.

C.4.0 **Tests for Mixer function**

C.4.1 After all calibration procedures are completed, perform the Pressure Balancing Module test procedure (see Test Procedure Section for Pressure Balancing Module).

C.4.2 The Air/Oxygen Mixer is now calibrated and ready for use.

C.4.3 To reassemble to the Infant Flow™ enclosure see the Disassembly and Re-assembly Section.

DISASSEMBLY AND RE-ASSEMBLY

General procedures - Before servicing, be sure all exterior connections such as the electrical power cord, gas lines etc are disconnected.

D.1.0 **Removal of the Air/Oxygen Mixer from the Infant Flow™ enclosure**

D.1.1 Remove the four M3 x 6mm raised countersunk screws that secure the top cover of the Infant Flow™ driver and the four M3 x 8mm pan head screws that secure the rear cover plate.

D.1.2 Using 3/16" Allen wrench remove the two screws, Part No S3630, which hold the Rail mount/gas inlet plate on the back of the mixer and slide the plate back and off of the O-rings.

D.1.4 Using a 3/16" or 1/8" Allen key remove the pole mount bracket from the side of the Infant Flow™ driver. The mixer/flowmeter assembly can now be removed from the lower housing.

D.2.0 **Removal of the Flowmeter block from the mixer**

D.2.1 Using a 9/64" Allen wrench, remove the two screws, Part No S3579, from the side of the flowmeter block. Pull the flowmeter block away from the Mixer.

D.2.2 Save the O-ring, Part No S3578, located between flowmeter block and Mixer for re-assembly.

D.3.0 Disassembly into 3 major modules: Proportioning Module, Pressure Balancing Module and Alarm Module

D.3.1 To remove the Alarm Module, Part No S3604, use a 7/64" Allen wrench to remove the two fixing screws, Part No S3624, underneath the module (see figure 11).

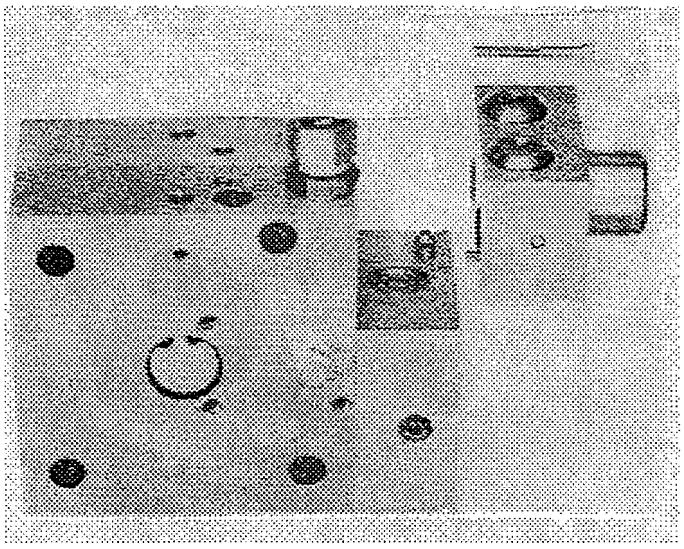

Figure 11 - The Alarm Module being taken off Mixer

D.3.2 Slide the Alarm Module straight back to clear the bypass nipple, Part No 3547, and lift the assembly off of the Mixer.

D.3.3 Remove the overlay from the faceplate and remove the two screws, Part No S3559, from the faceplate. This enables the removal of the faceplate from the mixer.

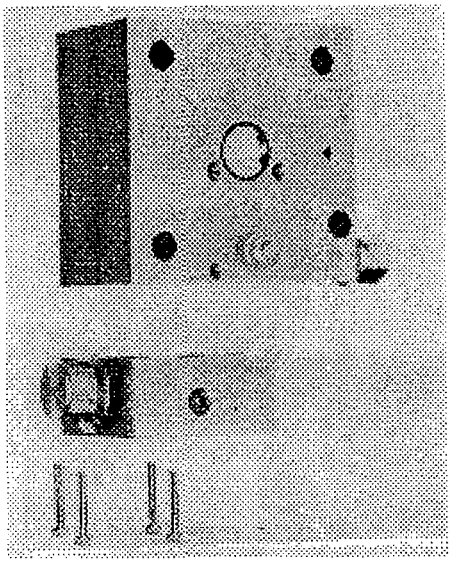

Figure 12 - Proportioning Module removal

D.3.4 Using a 9/64" Allen wrench, remove the four screws, Part No S3550 from the Proportioning Module, Part No S3502, and separate the Proportioning Module from the Pressure Balancing Module, making sure not to displace the O-rings (see figure 12).

Proportioning Module (see figure 8)

D.4.0 **Disassembly**

D.4.1 Using either a 1/16" or 5/64" Allen wrench, release the control knob, Part No S3538, by removing the set screw(s), Part No S223, then pull off the knob.

D.4.2 Insert special tool AT2 into the front seat, Part No S3532, locating holes. Use a 1/2" open end wrench to turn AT2 and remove the front seat.

D.4.3 With the front seat removed the double tapered needle, Part No S3541, will fall out.

D.4.4 Turn the module over to the rear seat, Part No S3542.

D.4.5 Insert special tool AT3 into rear seat locking nut, Part No S3543, and loosen using a 3/4" open end wrench.

D.4.6 With the locking nut loosened, insert special tool AT2 into the rear seat unscrew and remove the rear seat.

D.4.7 The front seat, rear seat and proportioning block can now be serviced.

D5.0 **Re-assembly of Proportioning Module**

D.5.1 Before reassembling the Proportioning Module inspect all O-rings and replace any O-ring that is cut, flat or worn and apply a light coating of Krytox to the front and rear seat O-rings.

D.5.2 Using special tool AT2, install the front seat, Part No S3532, into front seat port (the front of the proportioning block is identified by the presence of two stop pins), making sure not to tear the O-ring. Do not install the knob at this time.

D.5.3 Turn the adjustment shaft, Part No S3533, counter clockwise until resistance is felt.

D.5.4 Place the Proportioning Module front seat down.

NOTE: The module must be level, which may be accomplished by either placing the module into a vice or positioning it on two level blocks.

D.5.5 Drop the double tapered needle, Part No S3541, into the rear seat part and make sure that the needle is standing up straight in the centre of the valve bore.

D.5.6 Install the rear seat, Part No S3542, into the rear seat port, working it carefully so that the needle stays centred. Using special tool AT2 (hand tighten only), screw the rear seat down (about 6 turns) past the first resistance until contact is made with the needle. In this position, back off 1/2 turn.

D.5.7 Calibrate the Proportioning Module (see Calibration Section for Proportioning Module).

Pressure Balancing Module (see figure 3)

D.6.0 Disassembly of Pressure Balancing Module

D.6.1 For disassembly of the Pressure Balancing Module the Proportioning Module, Alarm Module and faceplate must be removed.

D.6.2 Using a 3/16" Allen wrench, remove the 4 screws, Part No S3507, from the air block, Part No S3505.

D.6.3 The module comes apart into 3 sections: air block, oxygen block and diaphragm assembly.

NOTE: Disassembly, re-assembly and calibration of the air block and oxygen block are identical.

D.6.4 Using a pair of tru-arc pliers, remove the tru-arc ring, Part No S3565.

D.6.5 The cover disc, Part No S3564 will pop up with the spring, Part No S3515, and the regulator needle, Part No S3514 can be removed.

D.6.6 Using 5/64" Allen wrench, loosen set screw, Part No S3518 from side of block.

NOTE: It is not necessary to completely remove the screw from the block.

D.6.7 Using special tool AT1 remove the eccentric adjuster, Part No S3516.

D.6.8 The regulator seat, Part No S3512, can now be removed from either end.

D.6.9 The seat and seat bore can now be serviced.

Section 12

Summary of Symbols

The following international standard symbols are used on the EME Infant Flow™ Driver and in this manual. It is essential that all users of the equipment have a firm understanding of the symbols.

Symbol	Explanation
	Class 1, type B Equipment
	Alternating Current
	Earth (Ground)
	Alarm
	Alarm cancel
	Off, Power disconnection from mains
	On, Power connection to mains

Section 13

WARRANTY

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This is the standard warranty for all products manufactured or supplied by EME (Electro Medical Equipment) Limited (hereinafter referred to as EME) and is extended only to the buyer purchasing the said product directly from the company or from an authorised dealer, distributor or agent as new merchandise.

All products supplied by EME are warranted for a period of one year from the date of installation or eighteen months from the date of delivery (whichever comes sooner) to be free from manufacturing defects and to conform to the description thereof contained in the relevant Operation and Routine Maintenance Manual, except that such warranty is limited to thirty (30) days with respect to rubber goods.

EME's sole obligation under this warranty is limited to the replacement or repair of the product or parts thereof which upon examination are found to contain manufacturing defects or not to conform to the description thereof contained in the relevant manual. EME will not be liable for consequential damages.

The foregoing warranty shall not apply if the product or any part thereof has (i) been repaired or altered by anyone other than an authorised representative of EME without written consent (ii) subjected to abuse, misuse, negligence or accident (iii) operated under conditions other than normal use (iv) the prescribed periodic maintenance and/or services have not been performed as specified in the relevant manual.

There are no warranties which extend beyond this warranty and the description of the products contained in the relevant Operation and Routine Maintenance Manuals. EME makes no warranty as to merchantability with respect to the products. This warranty is given in addition to statutory warranty and in no way affects the purchaser's statutory rights.

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